



Office of Strategic Operation and Regulatory Affairs/Freedom of Information Group
Refer to: Control Number 082720107066 and PINDQP6

APR 14 2011

Justin Crow
Virginia Department of Health Professions
9960 Mayland Drive, Suite 300
Henrico, VA 23233

Dear Mr. Crow:

I am responding to your August 31, 2010 Freedom of Information Act (FOIA) request addressed to the Philadelphia Regional Office (RO-3). The regional office forwarded your request and responsive documents to me because of my responsibility under the FOIA. Within your correspondence you requested the following information:

1. Complaint investigation involving Virginia medical/clinical laboratories for the period beginning January 1, 2005 and ending December 31, 2010;
2. Conditional deficiencies for the period beginning January 1, 2005 and ending December 31, 2010, the 5 most frequently cited conditional deficiencies in Virginia and
3. Immediate Jeopardy for the period beginning January 1, 2005 and ending December 31, 2010, the number of times "immediate jeopardy" was called on laboratories in Virginia.

After careful consideration of the documents submitted to me, a total of 51 pages, and in response to item one (1), I have determined to release eight (8) pages to you, in their entirety, and deny you access to portions of 29 of the released pages, pursuant to Exemption (b)(6) & (b)(7)(C) of the FOIA (5 U.S.C. § 552(b)(6) & (b)(7)(C)). I have also determined to deny you access to portions of 14 pages, pursuant to (Exemption (b)(6), (b)(7)(C) & (b)(7)(D) of the FOIA (5 U.S.C. § 552(b)(6), (b)(7)(C) & (b)(7)(D)).

In response to item two (2) of your request, I have been informed that data was only available from December 2006 to present for the following five (5) most frequently cited conditional deficiencies in Virginia: 493.1403 (74 times), Laboratory Director; 493.1250 (39 times), Analytic Systems; 493.1421 (37 times), Testing Personnel; 493.803 (33 times), PT Participation and 493.803 (33 times), PT Enrollment.

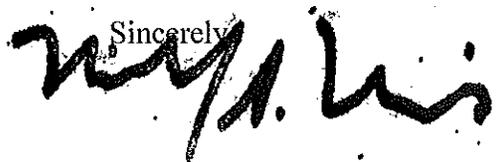
In response to item three (3) of your request, the number of times "immediate jeopardy" was called on laboratories were 493.1403 (8 times), Laboratory Director; 493.1250 (5 times), Analytic Systems; 493.1421 (4 times), Testing Personnel; 493.803 (3 times), PT Participation and 493.1290 (3 times), Post Analytic Systems.

Exemption (b)(6) permits a Federal agency to withhold information and records about individuals in "personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." I have weighed the public interest in disclosure against the harm to the privacy interest of the subject individuals. I have taken into consideration that the Supreme Court has held public interest in disclosure to be limited, in this context, to the public interest that would be served by shedding light on the agency's performance of its statutory duties. I have concluded that the personal privacy interests of the subject individuals outweigh the public interest in disclosure in this particular matter.

Exemption (b)(7)(C) protects from disclosure of "records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information . . . could reasonably be expected to constitute an unwarranted invasion of personal privacy."

Exemption (b)(7)(D) provides protection for "records of information compiled for law enforcement purposes [which] could reasonably be expected to disclose the identity of a confidential source, including a state, local, or foreign agency or authority or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source."

If you have reason to disagree with this decision, you may appeal. Your appeal should be mailed within 30 days of the date of this letter to: The Deputy Administrator, Centers for Medicare & Medicaid Services, Room C5-16-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. Please mark your envelope "Freedom of Information Act Appeal," and enclose a copy of this letter.

Sincerely,


Michael S. Marquis
Director
Freedom of Information Group

ACTS CLIA Laboratories in Virginia - Complaint/Incident Investigation Log

Printed: 09/09/2010

01/01/2005 to 12/31/2010 (Grouped By Provider)

Intake Number/ Rcvd End Ackd. †	Survey Start/Interval	Survey Exit Days*	Due Date	Inv Complete	Overall Finding	Event ID	Closed Date	Deficiency Cited - S/S	Activities (Complete Date)
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AAA WOMEN FOR CHOICE

✓ Facility ID: VA22011493	VA00016633	06/26/2009	06/26/2009	09/17/2009	83††	08/31/2009	Substantiated	F65Y11 05/04/2010	Federal - Linked to This Intake: D1000-CERTIFICATE OF WAIVER TESTS	Schedule Onsite Visit-07/22/2009
Non-IJ				09/17/2009		09/17/2009				

ALEXANDRIA WOMEN'S HEALTH CLINIC

✓ Facility ID: VA22011310	VA00016197	04/22/2009	05/26/2009	05/26/2009	34	06/25/2009	Substantiated	62SB11 08/27/2009	Federal - Linked to This Intake: D1000-CERTIFICATE OF WAIVER TESTS	Schedule Onsite Visit-05/27/2009
Non-IJ				05/27/2009		05/27/2009				

ANNANDALE WOMEN AND FAMILY CENTER

Facility ID: VA22005608 - Provider Number: 49D0883911	VA00016196	04/22/2009	09/16/2009	09/16/2009	147††	06/25/2009	Substantiated	Y22Q11 05/04/2010	Federal - Linked to This Intake: D1000-CERTIFICATE OF WAIVER TESTS	Schedule Onsite Visit-09/15/2009
Non-IJ				09/16/2009		09/16/2009				

BIOMAT USA, INC

✓ Facility ID: VA22000474 - Provider Number: 49D1023484	VA00011894	06/13/2007	06/13/2007	07/16/2007	33	08/16/2007	Unsubstantiated	1YK711 07/24/2007	No deficiencies cited	Schedule Onsite Visit-07/27/2007
Non-IJ				07/16/2007		07/16/2007				

BOSTWICK LABORATORIES, INC

✓ Facility ID: VA22003171 - Provider Number: 49D0966000	VA00012755	11/07/2007	11/07/2007	11/09/2007	2	01/15/2008	Substantiated	US3N11 05/04/2010	Federal - Linked to This Intake: D5207-COMMUNICATIONS D5391-PREANALYTIC SYSTEMS QUALITY ASSESSMENT	Schedule Onsite Visit-11/09/2007 Electronic Contact-05/04/2010
Non-IJ									Federal - Not Related to any Intakes: D5300-PREANALYTIC SYSTEMS D5393-PREANALYTIC SYSTEMS QUALITY ASSESSMENT D6118-TECHNICAL SUPERVISOR RESPONSIBILITIES	

VA00017413	11/05/2009	11/09/2007	308	11/09/2007		12/16/2008				
✓ No Action Necessary										

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ACTS CLIA Laboratories in Virginia - Complaint/Incident Investigation Log
01/01/2005 to 12/31/2010 (Grouped By Provider)

Printed: 09/09/2010

Activities
(Complete Date)

Deficiency Cited - S/S

Event ID
Closed Date

Overall
Finding

Survey Start/Interval
Due Date

Survey Exit Days*
Inv Complete

Survey Start/Interval
Due Date

Survey Exit Days*
Inv Complete

Survey Start/Interval
Due Date

Survey Exit Days*
Inv Complete

BRISTOL LABORATORIES, LLC

Facility ID: VA22009928 - Provider Number: 49D1086576

750

08/20/2008

No Action Necessary

CARILION STONEWALL JACKSON HOSPITAL

Facility ID: VA22003916 - Provider Number: 49D0232782

06/29/2007

1DRY11

Federal - Not Related to any Intakes:
D5805-TEST REPORT

Schedule Onsite
Visit-07/27/2007

Non-IJ

07/27/2007

CHILDRENS HEALTH CENTER AT OAKBROOKE

Facility ID: VA22001261 - Provider Number: 49D1008132

05/27/2008

R9VO11

No deficiencies cited

Electronic
Contact-07/22/2010
Schedule Onsite
Visit-04/24/2008
Electronic
Contact-03/25/2008

Non-IJ Medium

04/22/2010

CHILDRENS HOSPITAL OF THE KINGS

Facility ID: VA22000955 - Provider Number: 49D0015998

06/30/2008

Unsubstantiated

No deficiencies cited

Schedule Onsite
Visit-04/24/2008
Electronic
Contact-03/25/2008

Non-IJ



*duplicate due
re work done
to
re work done
to*

04/24/2008

FAIRFAX MEDICAL LABORATORIES INC

Facility ID: VA22001845 - Provider Number: 49D0221827

03/20/2008

3RMD11

Federal - Linked to This Intake:
D1000-CERTIFICATE OF WAIVER TESTS

Schedule Onsite
Visit-05/29/2009

Non-IJ

08/27/2009

FALLS CHURCH HEALTH CENTER

Facility ID: VA22011309

04/22/2009

36

Substantiated

08/27/2009

Federal - Linked to This Intake:
D1000-CERTIFICATE OF WAIVER TESTS

Schedule Onsite
Visit-05/29/2009

Non-IJ

05/28/2009

05/28/2009

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ACTS CLIA Laboratories in Virginia - Complaint/Incident Investigation Log

Printed: 09/09/2010

01/01/2005 to 12/31/2010 (Grouped By Provider)

Intake Number/ Rcvd End Ackd. † Survey Start/ Interval Due Date Overall Event ID Deficiency Cited - S/S Activities
 Priority Survey Exit Days* Inv Complete Finding Closed Date (Complete Date)

FAUQUIER HOSPITAL INC

Facility ID: VA22003447 - Provider Number: 49D0223595

VA00018875	07/22/2010	03/19/2010	-125††	01/30/2010	Unsubstantiated	GF1B11	Federal - Not Related to any Intakes: D5411-TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT D5805-TEST REPORT	Schedule Onsite Visit-03/19/2010
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Non-IJ

KEN J TOMPKINS MD

Facility ID: VA22001711 - Provider Number: 49D0861451

VA00015006	09/22/2008	09/22/2008	16	11/26/2008	Substantiated	J9K611 08/27/2008	Federal - Linked to This Intake: D5805-TEST REPORT D5891-POSTANALYTIC SYSTEMS QUALITY ASSESSMENT D6076-LABORATORY DIRECTOR D6078-LABORATORY DIRECTOR QUALIFICATIONS D6079-LABORATORY DIRECTOR RESPONSIBILITIES	Schedule Onsite Visit-10/08/2008
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Non-IJ

KEN J TOMPKINS, MD

Facility ID: VA22000043 - Provider Number: 49D1021651

VA00015007	09/22/2008	09/22/2008	127††	11/26/2008	Substantiated	97VK11 08/27/2008	Federal - Linked to This Intake: D5607-HISTOPATHOLOGY D5800-POSTANALYTIC SYSTEMS D5805-TEST REPORT D5891-POSTANALYTIC SYSTEMS QUALITY ASSESSMENT D6076-LABORATORY DIRECTOR D6078-LABORATORY DIRECTOR QUALIFICATIONS D6079-LABORATORY DIRECTOR RESPONSIBILITIES Federal - Not Related to any Intakes: D5787-TEST RECORDS	Schedule Onsite Visit-10/08/2008
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Non-IJ

LABCORP OF AMERICA HOLDINGS

Facility ID: VA22002946 - Provider Number: 49D0230192

VA00010091	08/25/2006	08/25/2006	1,476			08/25/2006		
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No Action Necessary

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ACTS CLIA Laboratories in Virginia - Complaint/Incident Investigation Log

Printed: 09/09/2010

01/01/2005 to 12/31/2010 (Grouped By Provider)

Intake Number/ Rcvd End Ackd. †	Survey Start/ Interval	Survey Exit Days*	Due Date	Overall Finding	Event ID	Closed Date	Deficiency Cited - SIS	Activities (Complete Date)
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LABORATORY CORPORATION OF AMERICA
Facility ID: VA22001126 - Provider Number: 49D0920855
 VA00010486 11/02/2006 11/02/2006 1,407 11/02/2006
 No Action Necessary

LABORATORY CORPORATION OF AMERICA
Facility ID: VA22001637 - Provider Number: 49D0668741
 VA00014563 07/01/2008 07/01/2008 08/15/2008 45 09/04/2008 Substantiated ED8Z11 Federal - Linked to Another Intake of this Survey: D5805-TEST REPORT Schedule Onsite Visit-08/05/2008
 Non-IJ 08/15/2008 08/15/2008 09/04/2008 Substantiated ED8Z11 Federal - Linked to This Intake: D5805-TEST REPORT Schedule Onsite Visit-08/05/2008

VA00014822 06/19/2008 08/20/2008 09/05/2008 17 10/23/2008 Unsubstantiated E3WQ11 No deficiencies cited Schedule Onsite Visit-08/20/2008
 Non-IJ 09/05/2008

VA00017175 10/05/2009 339†† 11/19/2009
 Non-IJ

LABORATORY CORPORATION OF AMERICA
Facility ID: VA22007262 - Provider Number: 49D1064749
 VA00014513 06/19/2008 06/19/2008 812 06/27/2008
 No Action Necessary

MONTGOMERY REGIONAL HOSPITAL
Facility ID: VA22001516 - Provider Number: 49D0231664
 VA00016624 06/25/2009 02/17/2010 237†† 08/09/2009 Unsubstantiated EGJ211 Federal - Not Related to any Intakes: D5413-TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT, D5431-MAINTENANCE AND FUNCTION CHECKS D5791-ANALYTIC SYSTEMS QUALITY ASSESSMENT Schedule Onsite Visit-02/17/2010
 Non-IJ 02/17/2010 02/17/2010

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 * Interval Days is the number of days between the Received End Date and Survey Start Date.
 LogFac: rpt 03/02 Page 4 of 8

ACTS CLIA Laboratories in Virginia - Complaint/Incident Investigation Log

Printed: 09/09/2010

01/01/2005 to 12/31/2010 (Grouped By Provider)

PIEDMONT PEDIATRICS, INC
 Facility ID: VA22001177 - Provider Number: 49D0897505
 VA00010145 08/31/2006 08/31/2006 1,470 Unsubstantiated 09/07/2006
 No Action Necessary

PLANNED PARENTHOOD OF METROPOLITAN
 Facility ID: VA22002334 - Provider Number: 49D0943753
 VA00015720 02/09/2009 02/09/2009 03/03/2009 22 04/14/2009 Substantiated 2FQS11 08/27/2009 Federal - Linked to This Intake: D5205-COMPLAINT INVESTIGATIONS
 Non-UJ 03/03/2009 03/03/2009 Schedule Onsite Visit-03/03/2009

PLASMACARE, INC
 Facility ID: VA22001407 - Provider Number: 49D1046110
 VA00016801 07/31/2009 405 08/27/2009
 No Action Necessary

PRIMARY HEALTH GROUP PC
 Facility ID: VA22003865 - Provider Number: 49D0679652
 VA00009785 06/21/2006 07/18/2006 07/10/2006 19 08/05/2006 Unsubstantiated G8QC11 09/12/2007 No deficiencies cited Schedule Onsite Visit-06/27/2006
 Non-UJ 07/10/2006 07/10/2006

QUEST DIAGNOSTICS NICHOLS INSTITUTE
 Facility ID: VA22003278 - Provider Number: 49D0221801
 VA00017764 01/05/2010 01/06/2010 247 01/06/2010
 No Action Necessary

SENTARA FAMILY MEDICINE AND URGENT CARE PHYSICI
 Facility ID: VA22001530 - Provider Number: 49D0670207
 VA00009514 04/24/2006 05/10/2006 1,599 05/10/2006 Agency Referral
 Non-CLIA Referral

SKIN LASER SURGERY CENTER, PC
 Facility ID: VA22011027 - Provider Number: 49D1096052

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ACTS CLIA Laboratories in Virginia - Complaint/Incident Investigation Log

01/01/2005 to 12/31/2010 (Grouped By Provider)

Printed: 09/09/2010

Intake Number/ Rcvd End Ackd. †	Survey Start/ Interval	Survey Exit Days*	Due Date	Overall Finding	Event ID Closed Date	Deficiency Cited - SIS	Activities (Complete Date)
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VA00018147	03/16/2010	44	04/30/2010		PS1Z11	No deficiencies cited	Schedule Onsite Visit-04/29/2010
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04/29/2010

SOUTHSIDE COMMUNITY HOSPITAL

Facility ID: VA22003929 - Provider Number: 49D00686045

VA00014431	06/05/2008	39	07/21/2008	Substantiated	NS7U11	Federal - Linked to This Intake: D5291-GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT D5429-MAINTENANCE AND FUNCTION CHECKS D5559-IMMUNOHEMATOLOGY D6076-LABORATORY DIRECTOR D6094-LABORATORY DIRECTOR	Schedule Onsite Visit-07/17/2008
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RESPONSIBILITIES
D6121-TECHNICAL SUPERVISOR
RESPONSIBILITIES
D6124-TECHNICAL SUPERVISOR
RESPONSIBILITIES

07/17/2008 07/17/2008

UNITED MEDICAL LABS INC

Facility ID: VA22001898 - Provider Number: 49D0222887

VA00012639	11/29/2006	1,380			12/15/2006		
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VA00015523	12/30/2008	12/30/2008	02/09/2009	41	03/06/2009	Substantiated	P93Z11 08/27/2006	Schedule Onsite Visit-01/31/2009
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Federal - Linked to This Intake:
D2148-CYTOTOLOGY
D2150-CYTOTOLOGY
D3009-FACILITIES
D5613-CYTOTOLOGY
D6076-LABORATORY DIRECTOR
D6079-LABORATORY DIRECTOR
RESPONSIBILITIES
D6108-LABORATORY TECHNICAL SUPERVISOR
D6111-TECHNICAL SUPERVISOR
QUALIFICATIONS

04/03/2009 04/03/2009

VCU HEALTH SYSTEM AUTHORITY - MCV HOSPITALS

Facility ID: VA22002253 - Provider Number: 49D1032785

VA00017379	11/03/2009	310			11/03/2006		
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ACTS CLIA Laboratories in Virginia - Complaint/Incident Investigation Log

Printed: 09/09/2010

01/01/2005 to 12/31/2010 (Grouped By Provider)

Intake Number/ Rcvd End Ackd. †	Survey Start/ Interval	Due Date	Overall Finding	Event ID Closed Date	Deficiency Cited - S/S	Activities (Complete Date)
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VIRGINIA HOSPITAL CENTER ARLINGTON
Facility ID: VA22000489 - Provider Number: 49D0224078

VA00011953	07/09/2007	09/06/2007	07/24/2007	15	09/11/2007	Unsubstantiated	WQZ811	09/12/2007	No deficiencies cited	Schedule Onsite Visit-07/27/2007
Non-IJ										
07/25/2007										

WHITE STONE FAMILY PRACTICE PC
Facility ID: VA22005466 - Provider Number: 49D0225083

VA00014799	08/15/2008	09/18/2008	34	10/21/2008	Substantiated	SUNR11	04/16/2009	Federal - Linked to This Intake: D5787-TEST RECORDS D6000-LABORATORY DIRECTOR D6029-DIRECTOR RESPONSIBILITIES D6063-LABORATORY TESTING PERSONNEL D6065-TESTING PERSONNEL QUALIFICATIONS	Schedule Onsite Visit-09/18/2008	
Non-IJ										

09/4/8/2008 09/4/8/2008

WILLIAM M HANDY, MD, FAAP
Facility ID: VA22004064 - Provider Number: 49D1048957

VA00010060	08/10/2006	08/14/2006	1,491	04/27/2010	No Action Necessary
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Total Providers Reported:	32
Total Complaints/Incidents Reported:	37

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ACTS CLIA Laboratories in Virginia - Complaint/Incident Investigation Log

01/01/2005 to 12/31/2010 (Grouped By Provider)

Printed: 09/09/2010

REPORT DEFINITIONS

Allegation Type	All	Received End Date	
Base time frame on	All		
Certif. at Time of Alleged Event	All		
Close Reason	All		
Date Range	01/01/2005 - 12/31/2010		
Intake Subtype	All		
Intake Type	Complaint		
Location Received	All		
Management Unit	All		
Onsite/Offsite	All		
Overall Findings	All		
Priority	All		
Provider Type	All		
Received By	All		
Responsible Team	All		
Show Outliers	No		
Sort By	Intake Number		
Source	All		
State Region	All		
Status	All		

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†† Survey Start Date (or current date) is later than Investigation Due Date.

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Printed: 09/23/2010 11:35:49AM
Due Date: 08/31/2009
Priority: Non-IJ

Intake ID: VA00016633
Facility ID: VA22011493 / LAB-NOCN
Provider Number:
State Region: 001

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: AAA WOMEN FOR CHOICE
Address: 9380-A FORESTWOOD LANE
City/State/Zip/County: MANASSAS, VA, 20110, MANASSAS CITY
Telephone: (703) 330-9312

License #:
Type: LAB-NO
Administrator:

[NO AO]

INTAKE INFORMATION

Taken by - Staff: BAGLEY, BRENDA
Location Received: TRAINING UNIT
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
External Control #:
CBER #:
SA Contact: STOLCIS, GREG
RO Contact: ARENDASH, ERIC
Responsible Team: ACUTE CARE
Source: Physician

Received Start: 06/26/2009 At 08:01
Received End: 06/26/2009 At 08:01
Received by: Written
State Complaint ID:
CIS Number:
Certificate at Time of Alleged Event: No CLIA Number

COMPLAINANTS

Name	Address	Home Phone	Work Phone	Link ID
	(b)(6), (b)(7)c			(b)(6), (b)(7)c

RESIDENTS/PATIENTS/CLIENTS - No Data

INTAKE DETAIL

Date of Alleged Event: Time: Shift:
Standard Notes: Complaint received from (b)(6), (b)(7)c in the area. See attached written complaint (including a page torn out of the telephone book yellow pages).
Extended RO Notes:
Extended CO Notes:

ALLEGATIONS

Category: General
Subcategory: Other
Findings: Substantiated: Federal deficiencies related to alleg are cited

Tags: D1000-CERTIFICATE OF WAIVER TESTS(493.15(c)) S/S: NOT SPECIFIED

Details: Complainant said that AAA Women for Choice is performing lab testing without a CLIA certificate.

Complainant questions who is the Medical Director of the lab (b)(6), (b)(7)c also wants to know who is advising the patients of the test results.

Findings Text: A Medical Facilities Inspector conducted an unannounced on-site Clinical Laboratory Improvement Amendments (CLIA) complaint investigation (VA16633) of AAA Women for Choice of Manassas laboratory in Manassas VA on September 17, 2009 at 10:30 AM. The laboratory does not have a CLIA certificate of any type.

Allegation states that the AAA Women for Choice is performing lab testing with out a CLIA certificate and wants to know who is the Medical Director.

During the complaint investigation, the inspector interviewed the facility Administrator and asked what laboratory tests are performed in-house. The Administrator stated they perform a urine hCG (Human Chorionic Gonadotrophin) pregnancy test using the IM Confirms II test kit by IM Isbell Martie Diagnostic, Inc. The IM Confirms II test kit is categorized as a CLIA waived test kit. There is no Medical Director at the facility, but a medical director is not required if only waived tests are performed at the lab.

The CLIA tag D1000 was cited as a standard level deficiency for the laboratory performing a waived test on

Printed: 09/09/2010 12:36:23PM
Due Date: 06/25/2009
Priority: Non-IJ

Intake ID: VA00016197
Facility ID: VA22011310 / LAB-NOCN
Provider Number:
State Region: 001

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: ALEXANDRIA WOMEN'S HEALTH CLINIC
Address: 101 S WHITING STREET, SUITE 215
City/State/Zip/County: ALEXANDRIA, VA, 22303, FAIRFAX
Telephone: (703) 370-0550

License #:
Type: LAB-NO
Administrator:

[No AO]

INTAKE INFORMATION

Taken by - Staff: BAGLEY, BRENDA
Location Received:
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
External Control #:
CBER #:
SA Contact: JONES, TC
STOLCIS, GREG
RO Contact: ARENDASH, ERIC
Responsible Team: ACUTE CARE
Source: Anonymous

Received Start: 04/22/2009 At 13:19
Received End: 04/22/2009 At 13:19
Received by: E-Mail
State Complaint ID:
CIS Number:
Certificate at Time of Alleged Event: No CLIA Number

COMPLAINANTS

Name	Address	Home Phone	Work Phone	Link ID
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(b)(6), (b)(7)c

RESIDENTS/PATIENTS/CLIENTS - No Data

INTAKE DETAIL

Date of Alleged Event: Time: Shift:

Standard Notes: Complaint was given to inspector during survey at another lab.

See allegation for details.

POC is attached.

Extended RO Notes:

Extended CO Notes:

ALLEGATIONS

Category: General
Subcategory: Certification /Unauthorized Testing
Findings: Substantiated:Federal deficiencies related to alleg are cited

Tags: D1000-CERTIFICATE OF WAIVER TESTS(493.15(c))	S/S: NOT SPECIFIED
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Details: Complainant stated that this facility is performing lab tests without a CLIA certificate. Review of the facility's website showed that they advertise blood and urine testing. Copy of website home page is attached.

Findings Text: A Medical Facilities Inspector conducted an unannounced on-site Clinical Laboratory Improvement Amendment (CLIA) investigation (#VA00016197) of the Alexandria Women's Health Clinic laboratory on May 27, 2009 from 1:00 PM to 2:00 PM. The laboratory is performing waived and non-waived tests without a CLIA registration certificate.

During the complaint investigation, the inspectors interviewed the co-owner of the facility. The inspector observed the lab performed the non-waived test for Rh (D) antigen blood typing test. The inspectors observed testing of three (3) waived tests including urinalysis by dipstick, hemoglobin by Hemocue analyzer, and a Quick Card urine pregnancy test kit.

The laboratory is cited with tag D1000 for performing non-waived lab tests in-house and reporting patient test results before obtaining a CLIA certificate of registration.

Printed: 09/09/2010 12:30:34PM
Due Date: 08/16/2007
Priority: Non-IJ

Intake ID: VA00011894
Facility ID: VA22000474 / LAB-CMPL
Provider Number: 49D1023484
State Region: LAB

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: BIOMAT USA, INC
Address: 15 WEST MERCURY BOULEVARD - SUITE C
City/State/Zip/County: HAMPTON, VA, 23666, HAMPTON CITY
Telephone: (757) 726-0501

License #:
Type: LAB-CM
Administrator:

[No AO]

INTAKE INFORMATION

Taken by - Staff: HANK, SALLY
Location Received:
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
External Control #:
CBER #:
SA Contact: STOLCIS, GREG
RO Contact:
Responsible Team: ACUTE CARE
Source: Resident/Patient/Client

Received Start: 06/13/2007 At 08:17
Received End: 06/13/2007 At 08:17
Received by: Written
State Complaint ID:
CIS Number:
Certificate at Time of Alleged Event: Compliance

COMPLAINANTS

Name	Address	Home Phone	Work Phone	Link ID
(b)(6), (b)(7)c				

RESIDENTS/PATIENTS/CLIENTS

Name	Admitted	Location	Room	Discharged	Link ID
(b)(6), (b)(7)c					

INTAKE DETAIL

Date of Alleged Event: Time: Shift:

Standard Notes: Complainant is a (b)(6), (b)(7)c (b)(6), (b)(7)c concerns are events that happened reportedly during 3/07 - 4/07. Concerns range from payment to donors, which includes a sweepstakes recruitment campaign, to various issues related to clinical procurement and processing procedures. The complaint allegations (attached) were issued in writing (received 6/8/07) and followed up by telephone on 6/11/07.

The complainant reported that (b)(6), (b)(7)c had already contacted the Better Business Bureau, Virginia Gaming, and local law enforcement about the use of sweepstake eligibility for donor payment.

6/8/07 Allegations discussed with Kim Beazley, CLIA surveyor. She stated that OLC had authority for investigating only the allegation related to protein lab testing. The other clinical issues should be referred to FDA. She also reported that payment and sweepstakes concerns were concerns outside of OLC or FDA jurisdiction.

6/8/07 The complainant was advised by telephone to contact the Virginia Department of Agriculture and Consumer Services (1-800-552-9963) regarding (b)(6), (b)(7)c concerns about the use of sweepstakes for donor recruitment. (b)(6), (b)(7)c was also advised to contact FDA (804-379-1627) regarding clinical issues unrelated to protein analysis. Complainant requested that the information and letters sent to OLC be returned (b)(6), (b)(7)c use within the referral process. This information was included with (b)(6), (b)(7)c letter of acknowledgement of the OLC complaint.

Extended RO Notes:
Extended CO Notes:

ALLEGATIONS

Category: Analytic
Subcategory: Other
Findings: Unsubstantiated: Allegation did not occur

Details: Complainant stated that (b)(6), (b)(7)c reported concerns about the use of sweepstake eligibility as part of donor payment practice and clinical practices for procurement to (b)(6), (b)(7)c BIOMAT corporate office during 3/07. Following this report, the complainant was denied opportunity twice in 4/07 to donate on the basis of the protein

ACTS Complaint/Incident Investigation Report

test being too low or too high (b)(6), (b)(7)c stated that in the (b)(6), (b)(7)c has been donating (b)(6), (b)(7)c has never had a protein problem and (b)(6), (b)(7)c has not changed (b)(6), (b)(7)c diet. The complainant believes that these findings have been falsely reported to deny (b)(6), (b)(7)c the opportunity to donate in retaliation (b)(6), (b)(7)c report of concerns to the corporate office.

Findings Text: The two (2) Medical Facilities Inspectors arrived at the facility on July 16, 2007 and met with the Facility Manager. The complaint allegation was discussed with the (b)(6), (b)(7)c. The inspectors reviewed the complainant's Electronic Medical Record (EMR). The complainant is identified by the facility as (b)(6), (b)(7)c (b)(6), (b)(7)c. The complainant's (b)(6), (b)(7)c records from December 2006 through June 2007 were reviewed.

Upon donation, each client is required to participate in a screening process. The client receives a Hematocrit and Total Protein tests, both of which are performed in house by the facility's testing personnel.

The facility's Serum Protein Electrophoresis Policy (SOP: 20.29D, edition 3) requires that a Serum Protein Electrophoresis (SPE) assay is to be performed on each plasma donor initially and every four (4) months thereafter. This test is performed at the Biomat USA laboratory located in Austin, Texas. The normal range for the SPE Total Protein assay is 6.0-9.0 g/dL. If the result of a client's SPE assay is abnormal, the client is deferred temporarily. The donor is removed from the program until repeat testing shows values within acceptable limits. The donor cannot be plasmapheresed again until a report of acceptable SPE test results has been received and the facility's Medical Director has reviewed the results and indicated the donor's acceptability to continue on the program. The review of normal tests results for determining continued suitability of the donor, must be performed by the Medical Director within twenty-one (21) days from the sample collection date.

The complainant presented to the facility on April 07, 2007 for donation. A SPE test specimen was collected at this time. The test results received indicated that the client had a Total Protein value from the SPE which was (b)(6), (b)(7)c. The client was placed on temporary deferral.

The complainant presented to the facility on April 14, 2007 for a follow-up SPE test. The test results received indicated that the client had a (b)(6), (b)(7)c from the SPE which was (b)(6), (b)(7)c. The client remained on temporary deferral.

The complainant returned to the facility on April 28, 2007 for a second follow-up test. The test results received from the SPE test were all within normal ranges. These test results were reviewed by the facility's Medical Director on May 10, 2007. The client was then removed from the temporary deferral list.

The complainant was able to successfully donate on May 10, 2007. The complainant has continued to donate at the facility since May 10, 2007.

The inspectors reviewed all in-house Total Protein quality control for the months of February through April 2007. The inspectors reviewed the facility's American Association of Bioanalysts (AAB) proficiency testing results from calendar years 2006 to the date of the investigation. The inspectors also reviewed a sample of testing personnel qualifications, training, and competency records.

The complaint was found to be unsubstantiated and no deficiencies were cited.

SURVEY INFORMATION

Event ID	Start Date	Exit Date	Team Members	Staff ID	Type of Survey
IYK711	07/16/07	07/16/07	Beazley, Kimberly F Ballas, Kay Logan, Chevonne	06384 13925 25040	Health

Intakes Investigated: VA00011894(Received: 06/13/2007)

Event ID	Exit Date	Tag	SUMMARY OF CITATIONS:	S/S
IYK711	07/16/2007	Federal - Not Related to any Intakes D0000-INITIAL COMMENTS		NOT SPECIFIED

EMTALA INFORMATION - No Data

Printed: 09/23/2010 11:40:53AM
Due Date: 01/15/2008
Priority: Non-IJ

Intake ID: VA00012755
Facility ID: VA22003171 / LAB-ACCR
Provider Number: 49D0966000
State Region: 001

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: BOSTWICK LABORATORIES, INC
Address: 4355 INNSLAKE DRIVE
City/State/Zip/County: GLEN ALLEN, VA, 23060, HENRICO
Telephone: (804) 967-9225

License #:
Type: LAB-ACI
Administrator:

[CAP]

INTAKE INFORMATION

Taken by - Staff: HANK, SALLY
Location Received:
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
External Control #:
CBER #:
SA Contact: BEAZLEY, KIMBERLY
RO Contact: ARENDASH, ERIC
Responsible Team: ACUTE CARE
Source: Resident/Patient/Client

Received Start: 10/09/2007 At 11:17
Received End: 11/07/2007 At 11:17
Received by: Hotline
State Complaint ID:
CIS Number:
Certificate at Time of Alleged Event: Accreditation

CAP

COMPLAINANTS

<u>Name</u>	<u>Address</u>	<u>Home Phone</u>	<u>Work Phone</u>	<u>Link ID</u>
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RESIDENTS/PATIENTS/CLIENTS

<u>Name</u>	<u>Admitted</u>	<u>Location</u>	<u>Room</u>	<u>Discharged</u>	<u>Link ID</u>
		(b)(6), (b)(7)c			

INTAKE DETAIL

Date of Alleged Event: Time: Shift:

Standard Notes: Complainant had diagnostic procedures of the bladder conducted on 8/30/07 at the Metroplex Surgicare Center in Bedford, Texas. The fluid and tissue specimens were sent to Bostwick Laboratories in Richmond, VA for analysis. The tissue biopsy specimen was lost.

Complainant reported that (b)(6), (b)(7)c not seeking legal action. The surgery center and the laboratory have advised (b)(6), (b)(7)c that (b)(6), (b)(7)c will not be billed for any expenses related to having repeated procedures for the bladder tissue biopsy. (b)(6), (b)(7)c concern is that specimens were lost related to a painful biopsy procedure and (b)(6), (b)(7)c doesn't want this to happen to anyone else. (b)(6), (b)(7)c stated that (b)(6), (b)(7)c knows that in the end, the point where the biopsy specimen was lost may not be able to be determined. (b)(6), (b)(7)c However, thinks the entire chain for handling the specimens sent between the two states needs to be examined to determine the possible weak points in the chain so that each point can be strengthened to avert error.

The complainant filed a written complaint with the SA in Texas related to the Metroplex Surgicare part of the specimen chain. (b)(6), (b)(7)c faxing a copy of the written complaint to the Texas SA simply for OLC information in reviewing the continued linkage in the chain in Virginia.

10/9/07 Received copy of complaint sent to SA in Texas (attached). SH

11/6/07 Received a copy (attached) of a letter from the (b)(6), (b)(7)c of the complainant to Bostwick Laboratories and dated 10/29/07. A handwritten note indicated that the complainant had not received any response from OLC. Voice mail message left on the complainant's telephone to call OLC for reassurance that the complaint had been received, but that OLC is waiting for direction from CMS. SH

11/6/07 Talked to complainant (b)(6), (b)(7)c reported that the SA in Texas had completed their investigation related to the Metroplex Surgicare and had notified (b)(6), (b)(7)c that (b)(6), (b)(7)c allegation that the specimen had been lost had been substantiated. (b)(6), (b)(7)c stated that although one might still raise question that the tissue specimen had not been included in the box with the requisition that was sent to Bostwick Labs by Metroplex Surgicare, Bostwick Labs failed to notify Metroplex Surgicare that the bladder tissue was not included in the package containing the specimens. SH

Printed: 09/23/2010 11:44:12AM
Due Date:
Priority: No Action Necessary

Intake ID: VA00017413
Facility ID: VA22003171 / LAB-ACCR
Provider Number: 49D0966000
State Region: 001

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: BOSTWICK LABORATORIES, INC
Address: 4355 INNSLAKE DRIVE
City/State/Zip/County: GLEN ALLEN, VA, 23060, HENRICO
Telephone: (804) 967-9225

License #:
Type: LAB-ACI
Administrator: CAP

INTAKE INFORMATION

Taken by - Staff: KING, ELIZABETH
Location Received: ACUTE CARE
Intake Type: Complaint
Intake Subtype: No State or Federal provider compliance issue
External Control #:
CBER #:
SA Contact: JONES, TC
RO Contact: ARENDASH, ERIC
Responsible Team: ACUTE CARE
Source: FDA

Received Start: 11/04/2009 At 14:40
Received End: 11/05/2009 At
Received by: Written
State Complaint ID:
CIS Number:
Certificate at Time of Alleged Event: Accreditation

COMPLAINANTS

Name	Address	Home Phone	Work Phone	Link ID
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(b)(6), (b)(7)c

RESIDENTS/PATIENTS/CLIENTS - No Data

INTAKE DETAIL

Date of Alleged Event: Time: Shift:

Standard Notes: Complainant is (b)(6), (b)(7)c with the submitting 2 complaints that pertain to laboratory practice, including staff qualifications and patient charges. (b)(6), (b)(7)c The complainant is

Complaint # 1 came from (b)(6), (b)(7)c and specifically identified Bostwick Laboratories as possibly offering "inducements" for accounts to send specimens to be processed. (b)(6), (b)(7)c stated "Bostwick Lab is currently paying physicians \$100 for every urine specimen sent in for PCA-3, but the catch is that the doctor has to send the biopsy that accompanies the urine test to Bostwick Labs in order to receive (b)(6), (b)(7)c \$100".

Complaint # 2 was an anonymous email sent to SA (b)(6), (b)(7)c Richmond Field Office. (b)(6), (b)(7)c was contacted by this analyst (b)(6), (b)(7)c (b)(6), (b)(7)c office did not investigate this complaint because the (b)(6), (b)(7)c ceased to provide information after the December email. In this complaint the staff qualifications were an issue particularly since the patients were required to undergo further testing at additional expense and time.

Anonymous complainant alleges the staff is not qualified in testing and the patients are requiring additional testing at their expense. Complainant alleges "lab assistants are in charge of processing instead of people with more experience, college degrees or certified. The most important process is left to unqualified technicians."

Complainant alleges the specimens are not being tested appropriately and outcome is a poor result requiring the test to be repeated at additional cost to the patient. In the anonymous e-mail the complainant alleges additional stains are being performed unnecessarily at the patient's expense. In particular (b)(6), (b)(7)c has stated that (b)(6), (b)(7)c ordered additional staining because of substandard staining in the lab of H&E staining". In addition, "Bostwick laboratories insist on using microwave processing which makes it very easy to burn the tissue and sends the slides to pathologists and, in turn, the billing department charges patients for steam charges when the tissue is over processed".

**SA recommends no further action ** Determined by Eric Arendash that RO will notify accrediting organization.

Extended RO Notes:
Extended CO Notes:

ALLEGATIONS - No Data

Printed: 09/23/2010 11:48:35AM

Due Date:

Priority: No Action Necessary

Intake ID: VA00014827

Facility ID: VA22009928 / LAB-CMPL

Provider Number: 49D1086576

State Region: LAB

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: BRISTOL LABORATORIES, LLC
Address: 1009 W STATE STREET - SUITE 2A
City/State/Zip/County: BRISTOL, VA, 24201, BRISTOL
Telephone: (276) 696-0144

License #:
Type: LAB-CM
Administrator: No AO

INTAKE INFORMATION

Taken by - Staff: BAGLEY, BRENDA
Location Received:
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
External Control #:
CBER #:
SA Contact: BEAZLEY, KIMBERLY
RO Contact:
Responsible Team: ACUTE CARE
Source: Anonymous

Received Start: 08/20/2008 At 09:27

Received End: 08/20/2008 At 09:27

Received by: E-Mail

State Complaint ID:

CIS Number:

Certificate at Time of Alleged Event: No Current Active Certificate

COMPLAINANTS

<u>Name</u>	<u>Address</u>	<u>Home Phone</u>	<u>Work Phone</u>	<u>Link ID</u>
(b)(6), (b)(7)c, (b)(7)d				

RESIDENTS/PATIENTS/CLIENTS - No Data

INTAKE DETAIL

Date of Alleged Event: Time: Shift:

Standard Notes: Email received from RO. New lab is pending. Per instructions from RO, issues non-regulatory. See attached copy of email.

Non-regulatory response letter sent to complainant via email.

Extended RO Notes:

Extended CO Notes:

ALLEGATIONS - No Data

EMTALA INFORMATION - No Data

ACTIVITIES - No Data

INVESTIGATIVE NOTES - No Data

CONTACTS - No Data

AGENCY REFERRAL - No Data

LINKED COMPLAINTS - No Data

NOTICES

Letters:

Notification:

<u>Created</u>	<u>Description</u>	<u>Date</u>	<u>Type</u>	<u>Party</u>	<u>Method</u>
08/20/2008	NON REGULATORY/Complainant				

PROPOSED ACTIONS - No Data

Closed: 08/20/2008

Reason: No Jurisdiction

END OF COMPLAINT INVESTIGATION INFORMATION

ENCL (7)

[Kremann, Kathleen M. (CMS/CMSO)]

From: (b)(6), (b)(7)c, (b)(7)d
Sent: Tue 8/19/2008 8:49 PM
To: Todd, Kathleen J. (CMS/CMSO)
Subject: Re: certification

it is Bristol laboratory it just got started it is on state street in bristol virginia

----- Original Message -----

From: "Todd, Kathleen J. (CMS/CMSO)" <Kathleen.Todd@cms.hhs.gov>
To: (b)(6), (b)(7)c, (b)(7)d >
Sent: Tuesday, August 19, 2008 6:34:10 PM
Subject: RE: certification

(b)(6), (b)(7)c, (b)(7)d

Thanks for the response. However, since no specific facility was mentioned in your e-mails, then CMS can take no further action. I urge you to report your concern to the appropriate State Agency.

From: (b)(6), (b)(7)c, (b)(7)d
Sent: Tue 8/19/2008 4:16 PM
To: Todd, Kathleen J. (CMS/CMSO)
Subject: Re: certification

(b)(6), (b)(7)c, (b)(7)d

----- Original Message -----

From: "Todd, Kathleen J. (CMS/CMSO)" <Kathleen.Todd@cms.hhs.gov>
To: (b)(6), (b)(7)c, (b)(7)d
Sent: Tuesday, August 19, 2008 10:22:45 AM

Subject: RE: certification

(b)(6), (b)(7)c, (b)(7)d

I am responding to an e-mail inquiry that you sent to the Food and Drug Administration (FDA). Your concern was forwarded to the Centers for Medicare & Medicaid Services (CMS) because CMS is responsible for the administration of the Clinical Laboratory Improvement Amendments (CLIA) program.

If you want to report a complaint about a specific CLIA facility, then you should contact the appropriate State Agency. You may obtain State Agency CLIA contact information from the following CMS Internet site: http://www.cms.hhs.gov/CLIA/downloads/CLIA_SA.pdf. You can remain anonymous.

If you have any additional CLIA questions, please feel free to call me at 410-786-3385.

Kathleen Todd, MT(ASCP)
Centers for Medicare & Medicaid Services
Survey and Certification Group
Division of Laboratory Services
7500 Security Blvd. (MS/S2-10-26)
Baltimore, Maryland 21244-1850

(b)(6), (b)(7)c, (b)(7)d

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t

Printed: 09/23/2010 11:55:18AM
Due Date: 06.29/2007
Priority: Non-IJ

Intake ID: VA00011563
Facility ID: VA22003916 / LAB-ACCR
Provider Number: 49D0232782
State Region: LAB

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: CARILION STONEWALL JACKSON HOSPITAL
Address: 1 HEALTH CIRCLE
City/State/Zip/County: LEXINGTON, VA, 24450, LEXINGTON CITY
Telephone: (540) 458-3311

License #:
Type: LAB-ACI
Administrator: CAP

INTAKE INFORMATION

Taken by - Staff: BAGLEY, BRENDA
Location Received: TRAINING UNIT
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
External Control #:
CBER #:
SA Contact: CARDEN, KATHRYN A.
RO Contact: SNYDER, BENJAMIN
ARENDASH, ERIC
Responsible Team: ACUTE CARE
Source: Physician

Received Start: 04/26/2007 At 11:41
Received End: 04/26/2007 At 11:41
Received by:
State Complaint ID:
CIS Number:
Certificate at Time of Alleged Event: Accreditation

COMPLAINANTS

<u>Name</u>	<u>Address</u>	<u>Home Phone</u>	<u>Work Phone</u>	<u>Link ID</u>
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(b)(6), (b)(7)c

RESIDENTS/PATIENTS/CLIENTS

<u>Name</u>	<u>Admitted</u>	<u>Location</u>	<u>Room</u>	<u>Discharged</u>	<u>Link ID</u>
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(b)(6), (b)(7)c

INTAKE DETAIL

Date of Alleged Event: Time: Shift:

Standard Notes: (b)(6), (b)(7)c, contacted the OLC on behalf of the physicians in Lexington Internists. The complaint regards the lab not sending lab results to the physician offices (b)(6), (b)(7)c provided the names of four patients and the studies ordered, but said that the office is not receiving any lab results for any their patients (b)(6), (b)(7)c also said that many other physicians in the community complain of the same problem.

(b)(6), (b)(7)c said that the Stonewall Jackson lab performs stat tests only and all others are sent to Carilion Consolidated Lab (CCL). CCL sends the results to Stonewall Jackson lab which is responsible for dispersing the results to the ordering physicians.

(b)(6), (b)(7)c said that the physicians can access the hospital computer for test results, but this is a time consuming process and usually occurs when the patient comes in for a follow up visit.

The problem with not receiving lab results has been discussed with the Stonewall Jackson (b)(6), (b)(7)c and with the president of the hospital, but no changes or improvements have occurred.

(b)(6), (b)(7)c said that the lab is supposed to send the reports via fax or courier which they were doing until several months ago.

5/7/09 Received faxed written CMS-2802A with approval for 45-day onsite survey from Eric Arendash, RO (attached). RO having difficulty with ACTS file.

5/9/07 Approval entered officially into ACTS by RO.

Extended RO Notes:

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: CHILDRENS HEALTH CENTER AT OAKBROOKE
Address: 500 DISCOVERY DRIVE - SUITE 101A
City/State/Zip/County: CHESAPEAKE, VA, 23320, CHESAPEAKE CITY
Telephone: (757) 668-9745

License #:
Type: LAB-ACI
Administrator: CAP

INTAKE INFORMATION

Taken by - Staff: GANNON, SHAWN
Location Received: COMPLAINT UNIT
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
External Control #:
CBER #:
SA Contact: BEAZLEY, KIMBERLY
RO Contact: ARENDASH, ERIC
Responsible Team: ACUTE CARE
Source: Family

Received Start: 03/24/2008 At 09:04
Received End: 03/24/2008 At 09:04
Received by: Hotline
State Complaint ID:
CIS Number:
Certificate at Time of Alleged Event: Accreditation
CAP

COMPLAINANTS

Name	Address	Home Phone	Work Phone	Link ID
(b)(6), (b)(7)c				

RESIDENTS/PATIENTS/CLIENTS

Name	Admitted	Location	Room	Discharged	Link ID
(b)(6), (b)(7)c					

INTAKE DETAIL

Date of Alleged Event: Time: Shift:

Standard Notes: Complainant is the (b)(6), (b)(7)c Hospital collecting station at Greenbriar did not obtain an adequate specimen in 2 instances and complainant is concerned about the unnecessary trauma sustained by (b)(6), (b)(7)c Complainant has attempted to lodge a grievance w/pt advocate, but pt advocate has not called back. Complainant wishes to lodge a complaint w/OLC.

Extended RO Notes: Email sent to RO from (b)(6), (b)(7)c stating complaint sent in error. Intake referred to CLIA and sent to Eric A. RO recommends no action necessary at this time. MDG

Extended CO Notes:

ALLEGATIONS

Category: Pre-Analytic
Subcategory: Specimen Handling
Findings: Unsubstantiated: Lack of sufficient evidence

Details: Per complainant (b)(6), (b)(7)c pt was found to have extra digits. Pt's (b)(6), (b)(7)c recommended that (b)(6), (b)(7)c studies be performed to check pt for any other possible (b)(6), (b)(7)c. On 02/06/08, pt was taken to the hospital's Health Care Center at Greenbriar for the blood specimen collection. Complainant was called the same day and it was requested that pt return to lab for another collection because there was not enough blood taken initially. When no results were forwarded to the ordering (b)(6), (b)(7)c by 03/13/08, the office investigated with the lab and learned that there was an insufficient quantity of blood collected for the test.

Phlebotomists

The complainant is concerned that the lab did not collect an adequate specimen on two different occasions and that the lab did not inform (b)(6), (b)(7)c that the test could not be performed. The complainant is also concerned that the lab mishandled one of the specimens causing a spillage of blood which created an insufficient quantity of the specimen in the first place. Complainant has spoken with the (b)(6), (b)(7)c of the facility, (b)(6), (b)(7)c who would only confirm that there was a mishandling of the specimen. The complainant also alleges that the facility told the (b)(6), (b)(7)c office that the lab was unable to contact the complainant because there was no answer on many occasions to have the pt brought back to the lab for the third time.

Printed: 09/23/2010 12:06:05PM
Due Date: 03/20/2008
Priority: Non-IJ

Intake ID: VA00013159
Facility ID: VA22001845 / LAB-ACCR
Provider Number: 49D0221827
State Region: LAB

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: FAIRFAX MEDICAL LABORATORIES INC
Address: 4200 PLEASANT VALLEY ROAD
City/State/Zip/County: CHANTILLY, VA, 20151, FAIRFAX
Telephone: (703) 691-8366

License #:
Type: LAB-ACI
Administrator: CAP

INTAKE INFORMATION

Taken by - Staff: GANNON, SHAWN
Location Received:
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
External Control #:
CBER #:
SA Contact: BEAZLEY, KIMBERLY
RO Contact: ARENDASH, ERIC
Responsible Team: ACUTE CARE
Source: Resident/Patient/Client

Received Start: 12/04/2007 At 15:10
Received End: 01/15/2008 At 15:10
Received by: Hotline
State Complaint ID:
CIS Number:
Certificate at Time of Alleged Event: Accreditation
CAP

COMPLAINANTS

<u>Name</u>	<u>Address</u>	<u>Home Phone</u>	<u>Work Phone</u>	<u>Link ID</u>
				(b)(6), (b)(7)c

RESIDENTS/PATIENTS/CLIENTS

<u>Name</u>	<u>Admitted</u>	<u>Location</u>	<u>Room</u>	<u>Discharged</u>	<u>Link ID</u>
		(b)(6), (b)(7)c			

INTAKE DETAIL

Date of Alleged Event: Time: Shift:

Standard Notes: Complainant reported to the lab to have a specimen drawn for lab tests. Complainant has some concerns about the lab. See allegations. Complainant declined to discuss concerns w/lab and requested that OLC conduct an investigation.

Extended RO Notes:

Extended CO Notes:

ALLEGATIONS

Category: Pre-Analytic

Subcategory: Other

Findings:

Details: Complainant stated the (b)(6), (b)(7)c reported to the lab to have a blood specimen drawn on 12/04/07. The complainant stated that the (b)(6), (b)(7)c whose name is not known cleaned the area (b)(6), (b)(7)c with alcohol and contaminated the cleaned area (b)(6), (b)(7)c. The complainant stated the (b)(6), (b)(7)c did not apply a clean pair of gloves before (b)(6), (b)(7)c palpated for a vein after cleaning the area. In addition, the gloves used by the (b)(6), (b)(7)c appeared to be dirty.

Findings Text:

Category: Facility Administration/Physical Environment

Subcategory:

Findings:

Details: Complainant stated that there was only one restroom available (b)(6), (b)(7)c in the lab. The restroom (b)(6), (b)(7)c did not have hot or cold running water.

Findings Text:

Printed: 09/23/2010 12:12:01PM
Due Date: 06/25/2009
Priority: Non-IJ

Intake ID: VA00016199
Facility ID: VA22011309 / LAB-NOCN
Provider Number:
State Region: 001

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: FALLS CHURCH HEALTH CENTER
Address: 900 S WASHINGTON STREET
City/State/Zip/County: FALLS CHURCH, VA, 22046, FALLS CHURCH CITY
Telephone: (703) 532-2500

License #:
Type: LAB-NO
Administrator:

No AD

INTAKE INFORMATION

Taken by - Staff: BAGLEY, BRENDA
Location Received:
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
External Control #:
CBER #:
SA Contact: JONES, TC
STOLCIS, GREG
RO Contact: ARENDASH, ERIC
Responsible Team: ACUTE CARE
Source: Anonymous

Received Start: 04/22/2009 At 13:27
Received End: 04/22/2009 At 13:27
Received by: E-Mail
State Complaint ID:
CIS Number:
Certificate at Time of Alleged Event: No CLIA Number

COMPLAINANTS

Name	Address	Home Phone	Work Phone	Link ID
		(b)(6), (b)(7)c		

RESIDENTS/PATIENTS/CLIENTS - No Data

INTAKE DETAIL

Date of Alleged Event: Time: Shift:
Standard Notes: Complaint given to inspector during survey at another lab.
See allegation for further information.
7/17/09 POC and attestation of cease testing document attached.

Extended RO Notes:
Extended CO Notes:

ALLEGATIONS

Category: General
Subcategory: Certification /Unauthorized Testing
Findings: Substantiated: Federal deficiencies related to alleg are cited

Tags: D1000-CERTIFICATE OF WAIVER TESTS(493.15(c))	S/S: NOT SPECIFIED
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Details: Complainant stated that this facility is performing lab tests without a CLIA certificate. Review of facility's website showed that clinic offers lab tests including Rh factor testing.

Information from facility website regarding services/testing provided and fee schedule is attached.

Findings Text: Two Medical Facilities Inspectors conducted an unannounced on-site Clinical Laboratory Improvement Amendment (CLIA) investigation (#VA00016199) of the Falls Church Health Center laboratory on May 28, 2009 from 1:00 PM to 2:00 PM. The laboratory is performing waived and non-waived tests without a CLIA certificate of registration.

During the complaint investigation, the inspectors interviewed the Director of Patient Services and a facility physician. The inspectors observed the lab performed the following non-waived tests: Rh (D) antigen blood typing test, a (b)(6), (b)(7)c
The inspectors observed testing of four (4) waived tests including a (b)(6), (b)(7)c

ENCL (11)

Printed: 09/23/2010 12:15:53PM
Due Date: 01/30/2010
Priority: Non-IJ

Intake ID: VA00018875
Facility ID: VA22003447 / LAB-ACCR
Provider Number: 49D0223595
State Region: LAB

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: FAUQUIER HOSPITAL INC
Address: 500 HOSPITAL DR
City/State/Zip/County: WARRENTON, VA, 20186, FAUQUIER
Telephone: (703) 349-0501

License #:
Type: LAB-ACI
Administrator:

CAP

INTAKE INFORMATION

Taken by - Staff: BAGLEY, BRENDA
Location Received: COMPLAINT UNIT
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
External Control #:
CBER #:
SA Contact: JONES, TC
RO Contact: ARENDASH, ERIC
Responsible Team: CLIA
Source: Family

Received Start: 07/22/2010 At 15:49
Received End: 07/22/2010 At 15:49
Received by: Written
State Complaint ID:
CIS Number:

Certificate at Time of Alleged Event: Accreditation
CAP

COMPLAINANTS

<u>Name</u>	<u>Address</u>	<u>Home Phone</u>	<u>Work Phone</u>	<u>Link ID</u>
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(b)(6), (b)(7)c

RESIDENTS/PATIENTS/CLIENTS

<u>Name</u>	<u>Admitted</u>	<u>Location</u>	<u>Room</u>	<u>Discharged</u>	<u>Link ID</u>
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(b)(6), (b)(7)c

INTAKE DETAIL

Date of Alleged Event: Time: Shift:

Standard Notes: ****Original complaint number, VA00017574, was deleted by RO according to (b)(6), (b)(7)c Alpine in Colorado. Copy of original intake obtained from surveyor who did the investigation and all information input into this complaint number. Original intake "End received date" was 12/16/09. Will attach this new intake to original survey shell.****

Original text:

Complainant is (b)(6), (b)(7)c of th (b)(6), (b)(7)c patient. Patient has a history of (b)(6), (b)(7)c and requires periodic lab work to determine efficacy of treatment.

Complainant is concerned that the lab results reported to the physician were not correct. Medications were adjusted accordingly and the patient developed new symptoms. Complainant said the patient had lab work done at 2 other labs and there was a discrepancy. The labs were done between 12/18/08-10/30/09.

According to the lab reports the hospital lab started using a different methodology to determine the TSH.

Determined that this is a CAP accredited lab. Complaint should be referred to the accrediting organization, according to CLIA administrative assistant. Notified Eric Arendash at RO via email on 12/30/09.

Extended RO Notes:

Extended CO Notes:

ALLEGATIONS

Category: Post-Analytic
Subcategory: Diagnostic Discrepancy/Erroneous Test Results
Findings: Unsubstantiated:Lack of sufficient evidence

Details: Complainant alleges the laboratory reported erroneous results to the (b)(6), (b)(7)c The patient's medications were adjusted accordingly and the complainant "feels" the patient is having symptoms that would have been controlled with the correct dosage of medication.

Printed: 09/23/2010 12:29:16PM
Due Date: 11/26/2008
Priority: Non-IJ

Intake ID: VA00015007
Facility ID: VA22000043 / LAB-CMPL
Provider Number: 49D1021651
State Region: LAB

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: KEN J TOMPKINS, MD
Address: 1157 FIRST COLONIAL ROAD - SUITE 300
City/State/Zip/County: VIRGINIA BEACH, VA, 23454, VIRGINIA BEACH CIT
Telephone: (757) 248-9799

License #:
Type: LAB-CM
Administrator:

INTAKE INFORMATION

Taken by - Staff: HANK, SALLY
Location Received:
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
External Control #:
CBER #:
SA Contact: BEAZLEY, KIMBERLY
RO Contact: ARENDASH, ERIC
Responsible Team: ACUTE CARE
Source: Physician

Received Start: 09/22/2008 At 11:40

Received End: 09/22/2008 At 11:40

Received by: Written

State Complaint ID:

CIS Number:

Certificate at Time of Alleged Event: Compliance

No AO

COMPLAINANTS

Name	Address	Home Phone	Work Phone	Link ID
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(b)(6), (b)(7)c

RESIDENTS/PATIENTS/CLIENTS - No Data

INTAKE DETAIL

Date of Alleged Event: Time: Shift:

Standard Notes: COMPLAINANT REQUESTED ANONYMITY

Complainant is a

(b)(6), (b)(7)c

9/22/08 Telephone follow-up with complainant to advise that the medical record concern would not be pursued as nonregulatory for Labs (b)(6), (b)(7)c reported that there were originally 3 physicians, including Ken Tompkins, who covered the two offices in Virginia and one in Kitty Hawk NC. The others were (b)(6), (b)(7)c The latter two are licensed in VA. Currently (b)(6), (b)(7)c -- (b)(6), (b)(7)c

2/23/09 Please refer to VA00015006 for actions regarding this lab.

3/10/09 Deficiency letter sent to lab is attached.

8/12/09 POC is attached.

Extended RO Notes:

Extended CO Notes:

ALLEGATIONS

Category: General

Subcategory: Unqualified Personnel

Findings: Substantiated: Federal deficiencies related to alleg are cited

Tags: D5607-HISTOPATHOLOGY(493.1273(d)(f))	S/S: NOT SPECIFIED
D6076-LABORATORY DIRECTOR(493.1441)	S/S: NOT SPECIFIED
D6078-LABORATORY DIRECTOR QUALIFICATIONS(493.1443(b))	S/S: NOT SPECIFIED
D6079-LABORATORY DIRECTOR RESPONSIBILITIES(493.1445(a)(b))	S/S: NOT SPECIFIED

Details: The owner, Ken J Tompkins, had his license to practice medicine/surgery in the state of Virginia suspended by

ACTS Complaint/Incident Investigation Report

complainant has received unsigned pathology reports for patients that have transferred to the complainant's practice -- (b)(6), (b)(7)c and (b)(6), (b)(7)c. In all three reports, the diagnosis was basal cell carcinoma. (Reports attached). The complainant noted that the PA, (b)(6), (b)(7)c who did the biopsies, initialed having seen the reported findings, and, that (b)(6), (b)(7)c the office initialed (b)(6), (b)(7)c had contacted the patients of the results.

Note: The complainant provided two reports, read in 2007 as examples of the signatures of the two (b)(6), (b)(7)c working at Ken J. Tompkins, (Ken Tompkins and (b)(6), (b)(7)c.

Findings Text: An unannounced CLIA complaint investigation was conducted at Ken J. Tompkins, MD Providence Road location on October 8, 2008, January 23, and January 26. During the surveys, the inspector interviewed the laboratory's (b)(6), (b)(7)c and the previous and current laboratory director. The inspector reviewed the laboratory's 2008 anatomic pathology reports, patient test logs, requisition forms, and procedure manual.

The allegation for this complaint is that not all pathology reports were signed by a physician.

At the beginning of the inspection, the inspector explained the allegations to the (b)(6), (b)(7)c and requested documentation that the laboratory notified the Office of Licensure and Certification (OLC) of a change in laboratory director since the current director's Virginia State Medical License was revoked in March 2008. The (b)(6), (b)(7)c confirmed that they were aware that the current director had (b)(6), (b)(7)c Virginia State Medical Licensure (b)(6), (b)(7)c stated that another physician in the practice had assumed the laboratory director responsibilities in March, but that they had not notified OLC of a change in director.

During the investigation, the inspector noticed the following two unrelated deficiencies:

The inspector requested to review an example of the laboratory's final test report form. During review, the inspector noted that the laboratory listed four testing locations on the form (3 in Virginia and 1 in North Carolina). The (b)(6), (b)(7)c confirmed in an interview that the laboratory did not identify which location performed the slide examination.

The inspector inquired about the testing performed at the laboratory's Hampton, VA location. The (b)(6), (b)(7)c called the location and during an interview between the (b)(6), (b)(7)c and the Hampton, VA location it was revealed that the Potassium Hydroxide (KOH) test procedure was performed there. The inspector then called OLC and confirmed that the Hampton, VA location of Ken J. Tompkins, MD does not hold any type of CLIA Certification. The surveyor inspected the Hampton location on January 27, 2009 and found no evidence of patient testing.

The laboratory has three physicians and one physician assistant. The current laboratory director's Virginia State Medical License has been revoked. The unofficial assistant laboratory director was on a month long vacation. The third physician only worked at the Providence Road location two days a week. The inspector requested to review the physicians and the physician assistant's patient logs. The (b)(6), (b)(7)c stated in an interview that the laboratory director did not see patients therefore he had no patient log. The inspector then randomly selected patients from the two remaining doctors and the physician assistant to review for signatures. Of the 57 final Anatomic Pathology Reports reviewed 43 were not signed by a qualified physician. Of the 43 not signed, 40 were from the (b)(6), (b)(7)c.

Summary: During the complaint investigation, the laboratory confirmed that not all final reports were signed. This complaint is substantiated.

An unannounced CLIA complaint investigation was conducted at Ken J. Tompkins, MD Providence Road location on October 8, 2008, January 23, and January 26. During the surveys, the inspector interviewed the laboratory's (b)(6), (b)(7)c and the previous and current laboratory director. The inspector reviewed the laboratory's 2008 anatomic pathology reports, patient test logs, requisition forms, and procedure manual.

The allegation for this complaint is that not all pathology reports were signed by a physician.

At the beginning of the inspection, the inspector explained the allegations to the (b)(6), (b)(7)c and requested documentation that the laboratory notified the Office of Licensure and Certification (OLC) of a change in

ACTS Complaint/Incident Investigation Report

the Virginia Board of Medicine, effective 3/12/08. (See attached copy of this action.) The complainant is concerned that he may still be practicing medicine/surgery; specifically, the complainant is concerned that the owner is reading pathology reports and functioning as the Director of the Laboratory.

It is also not clear who is supervising the PA practice if there is a PA in this office performing biopsies.

Findings Text: An unannounced CLIA complaint investigation was conducted at Ken J. Tompkins, MD First Colonial location on October 8, 2008, January 23, January 26, and January 27, 2009. During the surveys, the inspector interviewed the laboratory's (b)(6), (b)(7)c, and the previous and current laboratory director. The inspector reviewed the laboratory's 2008 anatomic pathology reports, patient test logs, requisition forms, and procedure manual.

The allegation for this complaint is that pathology slides were being read by unqualified testing personnel and that the laboratory was operating without a laboratory director.

At the beginning of the inspection, the inspector explained the allegations to the (b)(6), (b)(7)c and requested documentation that the laboratory notified the Office of Licensure and Certification (OLC) of a change in laboratory director since the current director's Virginia State Medical License was revoked in March 2008. The (b)(6), (b)(7)c at the First Colonial location confirmed that they were aware that the current director had lost his Virginia State Medical license (b)(6), (b)(7)c also produced signed (March 1 2008) documentation showing that another physician in the practice had agreed to resume the responsibilities of the Lab Director, but confirmed that they had not notified OLC of a change in director.

During survey it was noted that (b)(6), (b)(7)c was unavailable from September 15 to October 13, 2008. In interviews with the above mentioned (b)(6), (b)(7)c it was stated that when (b)(6), (b)(7)c was unavailable all slides were sent to a reference laboratory or held for (b)(6), (b)(7)c return. The inspector reviewed all available patient test requisitions, patient logs, and final anatomic pathology reports generated between September 15th and October 13th at the Hampton, Virginia location. The inspector reviewed 100 of 123 available reports and noted they they were performed when (b)(6), (b)(7)c was unavailable. The inspector and (b)(6), (b)(7)c reviewed examples of the reports and (b)(6), (b)(7)c stated that (b)(6), (b)(7)c could not say who read the histopathology slides. The inspector interviewed (b)(6), (b)(7)c on January 27, 2009 and inquired about who read the histopathology slides when (b)(6), (b)(7)c was unavailable. (b)(6), (b)(7)c could not say who read the slides. In an interview with the current laboratory director and (b)(6), (b)(7)c, it was noted that the person who reads the histopathology slides documents the results on the patient requisition form and are then transcribed onto the final anatomic pathology report. The inspector reviewed the requisitions generated during the above mentioned time frame and noted (b)(6), (b)(7)c hand witting on the forms. (b)(6), (b)(7)c confirmed that the witting belonged to

This evidence led the inspector to believe that the histopathology slides were read by (b)(6), (b)(7)c (b)(6), (b)(7)c lost his license to practice Medicine in March 2008.

During the investigation, the inspector noticed the following unrelated deficiencies:

The inspector inquired about the testing performed at the laboratory's Hampton, VA location. The (b)(6), (b)(7)c called the location and during an interview between the (b)(6), (b)(7)c and the Hampton, VA location it was revealed that the Potassium Hydroxide (KOH) test procedure was performed there. The inspector then called OLC and confirmed that the Hampton, VA location of Ken J. Tompkins, MD does not hold any type of CLIA Certification. The surveyor inspected the Hampton location on January 27, 2009 and found no evidence of patient testing.

During survey, it was noted that only (b)(6), (b)(7)c is qualified to read histopathology slides. During review of the final anatomic pathology reports, the inspector noted fifty-four (54) of 100 final reports with no testing personnel identifier. The inspector interviewed the laboratory director and (b)(6), (b)(7)c and neither could tell the inspector who read the histopathology slides.

Summary: During the complaint investigation, the laboratory confirmed that the laboratory failed to obtain an approved laboratory director and failed to ensure that only qualified personnel read histopathology slides. The complaint is substantiated.

Printed: 09/23/2010 12:31:06PM
Due Date: ~
Priority: No Action Necessary

Intake ID: VA00010091
Facility ID: VA22002946 / LAB-PEND
Provider Number: 49D0230192
State Region: 001

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: LABCORP OF AMERICA HOLDINGS
Address: 11835 FISHING POINT DRIVE SUITE 204
City/State/Zip/County: NEWPORT NEWS, VA, 23606, NEWPORT NEWS CI
Telephone: (804) 873-1258

License #:
Type: LAB-PEI
Administrator:

INTAKE INFORMATION

Taken by - Staff: BUCHANAN, LEONARD E.
Location Received:
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
External Control #:
CBER #:
SA Contact: CARDEN, KATHRYN A.
RO Contact:
Responsible Team:
Source: Resident/Patient/Client

Received Start: 08/16/2006 At 11:22
Received End: 08/25/2006 At 11:22

Received by: Written
State Complaint ID:

CIS Number:
Certificate at Time of Alleged Event: No CLIA Number

No AD

COMPLAINANTS

<u>Name</u>	<u>Address</u>	<u>Home Phone</u>	<u>Work Phone</u>	<u>Link ID</u>
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(b)(6), (b)(7)c

RESIDENTS/PATIENTS/CLIENTS

<u>Name</u>	<u>Admitted</u>	<u>Location</u>	<u>Room</u>	<u>Discharged</u>	<u>Link ID</u>
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(b)(6), (b)(7)c

INTAKE DETAIL

Date of Alleged Event: Time: Shift:

Standard Notes: Review by CMS determined that this is a draw station and we have no regulatory authority.

Extended RO Notes:

Extended CO Notes:

ALLEGATIONS - No Data

EMTALA INFORMATION - No Data

ACTIVITIES - No Data

INVESTIGATIVE NOTES - No Data

CONTACTS - No Data

AGENCY REFERRAL - No Data

LINKED COMPLAINTS - No Data

NOTICES

Letters:

<u>Created</u>	<u>Description</u>
08/25/2006	NON REGULATORY/Complainant

Notification:

<u>Date</u>	<u>Type</u>	<u>Party</u>	<u>Method</u>
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PROPOSED ACTIONS - No Data

Closed: 08/25/2006

Reason: No Jurisdiction

Printed: 09/23/2010 12:33:37PM
Due Date:
Priority: No Action Necessary

Intake ID: VA00010486
Facility ID: VA22001126 / LAB-PEND
Provider Number: 49D0920859
State Region: LAB

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: LABORATORY CORPORATION OF AMERICA
Address: 5130 DUKE STREET - SUITE 10
City/State/Zip/County: ALEXANDRIA, VA, 22304, ALEXANDRIA CITY
Telephone: (703) 823-6294

License #:
Type: LAB-PEI
Administrator:

INTAKE INFORMATION

Taken by - Staff: GANNON, SHAWN
Location Received:
Intake Type: Complaint
Intake Subtype: No State or Federal provider compliance issue
External Control #:
CBER #:
SA Contact: BAGLEY, BRENDA
RO Contact:
Responsible Team:
Source: Other State Agency

Received Start: 11/02/2006 At 11:24
Received End: 11/02/2006 At 11:24
Received by: Written
State Complaint ID:
CIS Number:
Certificate at Time of Alleged Event: Waiver

N: AO

COMPLAINANTS

<u>Name</u>	<u>Address</u>	<u>Home Phone</u>	<u>Work Phone</u>	<u>Link ID</u>
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(b)(6), (b)(7)c

RESIDENTS/PATIENTS/CLIENTS

<u>Name</u>	<u>Admitted</u>	<u>Location</u>	<u>Room</u>	<u>Discharged</u>	<u>Link ID</u>
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(b)(6), (b)(7)c

INTAKE DETAIL

Date of Alleged Event: Time: Shift:

Standard Notes: Complainant wrote (b)(6), (b)(7)c concerns about the manner in which staff persons treated (b)(6), (b)(7)c facility. Concerns were not of a regulatory nature.

Extended RO Notes:

Extended CO Notes:

ALLEGATIONS - No Data

EMTALA INFORMATION - No Data

DEEMED/RO APPROVAL INFORMATION - No Data

ACTIVITIES - No Data

INVESTIGATIVE NOTES - No Data

CONTACTS - No Data

AGENCY REFERRAL - No Data

LINKED COMPLAINTS - No Data

NOTICES

Letters:

<u>Created</u>	<u>Description</u>
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11/02/2006 NON REGULATORY/Complainant

Notification:

<u>Date</u>	<u>Type</u>	<u>Party</u>	<u>Method</u>
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Printed: 09/23/2010 12:36:01PM
Due Date: 09/04/2008
Priority: Non-IJ

Intake ID: VA00014563
Facility ID: VA22001637 / LAB-ACCR
Provider Number: 49D0668741
State Region: LAB

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: LABORATORY CORPORATION OF AMERICA
Address: 13900 PARK CENTER ROAD
City/State/Zip/County: HERNDON, VA, 20171, FAIRFAX
Telephone: (703) 742-3100

License #:
Type: LAB-ACI
Administrator:

CAP

INTAKE INFORMATION

Taken by - Staff: BAGLEY, BRENDA
Location Received: COMPLAINT UNIT
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
External Control #:
CBER #:
SA Contact: BEAZLEY, KIMBERLY
RO Contact: ARENDASH, ERIC
Responsible Team: ACUTE CARE
Source: Current Staff

Received Start: 06/27/2008 At 13:50
Received End: 07/01/2008 At 13:50
Received by: Hotline
State Complaint ID:
CIS Number:
Certificate at Time of Alleged Event: Accreditation

CAP

COMPLAINANTS

Name	Address	Home Phone	Work Phone	Link ID
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(b)(6), (b)(7)c

RESIDENTS/PATIENTS/CLIENTS - No Data

INTAKE DETAIL

Date of Alleged Event: Time: Shift:

Standard Notes: Complainant is the (b)(6), (b)(7)c Pediatrician's office is having difficulty obtaining laboratory results from blood tests that are performed by this lab.

Extended RO Notes:

Extended CO Notes:

ALLEGATIONS

Category: Pre-Analytic

Subcategory: Other

Findings: Substantiated: No deficiencies related to the alleg are cited

Details: Specimens are labelled at collection site with an incorrect ID number (ID number for another physician practice). The results then are not sent to the ordering physician.

Findings Text:

A Medical Facility Inspector conducted an unannounced on-site Clinical Laboratory Improvement Amendment (CLIA) complaint investigation (#VA00014563) of Laboratory Corporation of America in Herndon VA on August 15, 2008 from 10:30 AM to 4:30 PM. The laboratory is accredited by the College of American Pathologists (CAP) and operates under CLIA Certificate #49D0668741.

During the complaint investigation, the inspector interviewed the (b)(6), (b)(7)c and the (b)(6), (b)(7)c. The inspector reviewed the following documents: the Patient Service Technician (PST) re-training record, the HIPPA Security Policy, the Quality Assurance Committee meeting minutes from March 26, 08 and April 30, 08. There was no QA meeting in May 2008.

Re: Allegation that a specimen from the Leesburg Patient Service Center (PSC) was labelled with an incorrect account number for the physician practice that ordered the test. The test results were not sent to the ordering physician. In an interview with the inspector at 12:30 PM, the (b)(6), (b)(7)c stated the Leesburg PSC computer system had an incorrect default code number for a physician, and the (b)(6), (b)(7)c did not detect account code error before labelling the specimen tubes. As corrective action, the (b)(6), (b)(7)c was retrained on July 09, 08, and the LCM computer system was replaced on June 16, 2008.

Printed: 09/09/2010 12:38:46PM
Due Date: 09/04/2018
Priority: Non-IJ

Intake ID: VA00014564
Facility ID: VA22001637 / LAB-ACCR
Provider Number: 49D0668741
State Region: LAB

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: LABORATORY CORPORATION OF AMERICA
Address: 13900 PARK CENTER ROAD
City/State/Zip/County: HERNDON, VA, 20171, FAIRFAX
Telephone: (703) 742-3100

License #:
Type: LAB-ACI
Administrator: CAP

INTAKE INFORMATION

Taken by - Staff: BAGLEY, BRENDA
Location Received: COMPLAINT UNIT
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
External Control #:
CBER #:
SA Contact: BEAZLEY, KIMBERLY
RO Contact: ARENDASH, ERIC
Responsible Team: ACUTE CARE
Source: Physician

Received Start: 06/27/2008 At 13:57
Received End: 07/01/2008 At 13:57
Received by: E-Mail
State Complaint ID:
CIS Number:
Certificate at Time of Alleged Event: Accreditation

COMPLAINANTS

<u>Name</u>	<u>Address</u>	<u>Home Phone</u>	<u>Work Phone</u>	<u>Link ID</u>
		(b)(6), (b)(7)c		

RESIDENTS/PATIENTS/CLIENTS

<u>Name</u>	<u>Admitted</u>	<u>Location</u>	<u>Room</u>	<u>Discharged</u>	<u>Link ID</u>
		(b)(6), (b)(7)c			

INTAKE DETAIL

Date of Alleged Event: Time: Shift:
Standard Notes: Complaint received from the Maryland state agency via Eric Arendash, RO.
Documents provided by complainant are attached.
Extended RO Notes:
Extended CO Notes:

ALLEGATIONS

Category: Analytic
Subcategory: Other
Findings: Substantiated: Federal deficiencies related to alleg are cited

Tags: D5805-TEST REPORT(493.1291(c))	S/S: NOT SPECIFIED
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Details: A urine culture was sent to Lab Corp on 5/20/08. The (b)(6), (b)(7)c complainant called for results on 5/23/08 as none had been received. The complainant was informed that the specimen was not run due to an expired sample tube; however, no notification was received at the office until after the complainant called. The complainant insisted that the specimen be run. The results were entered on 5/23/08 and reported on 5/26/08. The results indicated that the patient's prostate infection was resistant to the antibiotic.

Findings Text:

A Medical Facility Inspector from the VA Department of Health, the Clinical Laboratory Improvement Amendment (CLIA) Unit, conducted an unannounced on-site complaint investigation (#VA00014564) of the Laboratory Corporation of America in Herndon VA on August 15, 2008 from 10:30 AM to 4:30 PM. The laboratory is accredited by the College of American Pathologists (CAP) and operates under CLIA Certificate #49D0668741.

During the complaint investigation, the inspector interviewed the (b)(6), (b)(7)c and

Printed: 09/23/2010 12:40:10PM
Due Date: 10/23/2008
Priority: Non-IJ

Intake ID: VA00014822
Facility ID: VA22001637 / LAB-ACCR
Provider Number: 49D0668741
State Region: LAB

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: LABORATORY CORPORATION OF AMERICA
Address: 13900 PARK CENTER ROAD
City/State/Zip/County: HERNDON, VA, 20171, FAIRFAX
Telephone: (703) 742-3100

License #:
Type: LAB-ACI
Administrator:

CAP

INTAKE INFORMATION

Taken by - Staff: BAGLEY, BRENDA
Location Received:
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
External Control #:
CBER #:
SA Contact: BEAZLEY, KIMBERLY
RO Contact: ARENDASH, ERIC
Responsible Team: ACUTE CARE
Source: Physician

Received Start: 08/19/2008 At 10:13
Received End: 08/19/2008 At 10:13
Received by: E-Mail
State Complaint ID:
CIS Number:
Certificate at Time of Alleged Event: Accreditation

COMPLAINANTS

Name	Address	Home Phone	Work Phone	Link ID
(b)(6), (b)(7)c				

RESIDENTS/PATIENTS/CLIENTS

Name	Admitted	Location	Room	Discharged	Link ID
(b)(6), (b)(7)c					

INTAKE DETAIL

Date of Alleged Event: Time: Shift:
Standard Notes: Complaint received from Kim Weaver, RO. Please see attached documents for details.
Extended RO Notes:
Extended CO Notes:

ALLEGATIONS

Category: Pre-Analytic
Subcategory: Specimen Handling
Findings: Unsubstantiated: Lack of sufficient evidence

Details: (b)(6), (b)(7)c sent a letter of complaint to the Maryland state agency which was forwarded to RO (b)(6), (b)(7)c. Complaint is that a specimen (biopsy) to confirm diagnosis and obtain clear margins was sent to LabCorp on May 1, 2008. It was received by LabCorp as evidenced by a form from LabCorp requesting information. When the results had not been received in a month (b)(6), (b)(7)c office called LabCorp and learned that nothing had happened.

(b)(6), (b)(7)c said that without being contacted the specimen (which apparently had no patient name on it) was sent back to (b)(6), (b)(7)c office in a container that was labeled for pap smears (b)(6), (b)(7)c (b)(6), (b)(7)c office did not accept the package as they had no knowledge that this was their patient. The package was sent back to LabCorp.

The office again contacted LabCorp for the results of the biopsy. The specimen had been sent back to the office and a name label was placed on the bottle. The specimen was picked up by LabCorp on May 22, 2008. After several more weeks with no results the office called LabCorp and learned that they could not find the specimen, but did have a record of it having been picked up by the second driver on May 22, 2008.

(b)(6), (b)(7)c has spoken with (b)(6), (b)(7)c at LabCorp, neither of whom can give (b)(6), (b)(7)c any further information.

Findings Text:

ACTS Complaint/Incident Investigation Report

FACILITY INFORMATION:

Name: LABORATORY CORPORATION OF AMERICA
 Address: 13900 PARK CENTER ROAD
 City/State/Zip/County: HERNDON, VA, 20171, FAIRFAX
 Telephone: (703) 742-3100

License #:
 Type: LAB-ACCR
 Administrator:

CAP

INTAKE INFORMATION

Taken by - Staff: ARENDASH, ERIC
 Location Received:
 Intake Type: Complaint
 Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
 External Control #:
 CBER #:
 SA Contact: BAGLEY, BRENDA
 JONES, TC
 RO Contact: ARENDASH, ERIC
 Responsible Team: ACUTE CARE
 Source: Physician

Received Start: 10/05/2009 At 07:15
 Received End: 10/05/2009 At 10:49
 Received by:
 State Complaint ID:
 CIS Number:
 Certificate at Time of Alleged Event: Accreditation

COMPLAINANTS

<u>Name</u>	<u>Address</u>	<u>Home Phone</u>	<u>Work Phone</u>	<u>Link ID</u>
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(b)(6), (b)(7)c

RESIDENTS/PATIENTS/CLIENTS - No Data

INTAKE DETAIL

Date of Alleged Event: Time: Shift:

Standard Notes: See attachment for complete description of complaint.

SA will need to contact complainant for further detailed information on specific tests delayed and dates supposed incidents occurred as mentioned in letter.

11/2/09 Eric Arendash (RO) said today that he had spoken with the physician office and they are satisfied with the lab's response to their complaint. Eric will input some notes regarding this complaint. No further action needed.

Extended RO Notes:

Extended CO Notes:

ALLEGATIONS

Category: Pre-Analytic
 Subcategory: Other
 Findings:
 Details:

Findings Text:

Category: Post-Analytic
 Subcategory: Other
 Findings:
 Details:

Findings Text:

AUG 19 2009

(b)(6), (b)(7)c

August 14, 2009

LabCorp, Inc.
James Henry, M.D.
13900 Park Center Road
Herndon, VA 2017

Office of the Medicare
Ombudsman
misdirected
AUG 25 2009
cmm

Dear Dr. Henry:

This letter is to inform you of the dissatisfaction that I still have with your laboratory. This is not the first letter of complaint I have sent to you. I am still not receiving the gratification that is needed to take care of my patients.

We are extremely frustrated with the fact that the Lab is not sending us results for pending tests for 3 or more months and when we call the wait time is enormous. We have tried to reach the regional manager and we have not had any cooperation. This has been happening for years and we want to make you aware that not receiving test results in a timely fashion does compromise patient care.

We would appreciate it if you could resolve this chronic issue with your lab that has frustrated us over the years.

Sincerely,

(b)(6), (b)(7)c

.brs

cc: Aetna, Cigna, Medicare, BlueCross Blue Shield, Mamsi

Printed: 09/23/2010

Due Date:

Priority: No Action Necessary

INTAKE INFORMATION

Intake Number: VA00014513

Facility ID: VA22007262

Provider Number: 49D1064749

State Region: LAB

FACILITY INFORMATION:

Name: LABORATORY CORPORATION OF AMERICA

Address: 112 ELDEN STREET, SUITE A

City/State/Zip/County: HERNDON, VA, 20170, FAIRFAX

Telephone: (804) 214-9290

License #:

Type: LAB-WAIV

Administrator:

INTAKE INFORMATION:

Intake Number: VA00014513

Taken by - Staff: GANNON, SHAWN

Location Received:

Intake Type: Complaint

Intake Subtype: No State or Federal provider compliance issue

CBER #:

SA Contact: BEAZLEY, KIMBERLY

RO Contact: ARENDASH, ERIC

Responsible Team: ACUTE CARE

Source: Current Staff

Received Start: 06/19/2008 At 09:45

Received End: 06/19/2008 At 09:45

Received by: Hotline

State Complaint ID:

CIS Number:

External Control #:

Certificate at Time of Alleged Event: Waiver *N, AO*

COMPLAINANTS:

<u>Name</u>	<u>Address</u>	<u>Work Phone</u>	<u>Home Phone</u>	<u>Cell Phone</u>
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(b)(6), (b)(7)c

Confidentiality Requested : N

Link ID: 08CYZK

INTAKE DETAIL:

Date of Alleged Event: Time: Shift:

Standard Notes: Complainant is the (b)(6), (b)(7)c Pediatrician's office is having difficulty obtaining laboratory results from blood tests that are performed by this lab.

Complaint intake needs to be under the main lab located at Herndon, VA. Will close this intake and reopen under that provider number.

Extended RO Notes:

Extended CO Notes:

duplicate complaint

ALLEGATIONS:

Category: Post-Analytic

Sub-category: Other

Details: Complainant stated that when its patients are directed to the collection station for the lab, the collection station uses an ID number for another practice when it labels Towne Pediatric patient's specimens. Consequently, the results of the specimen testing do not get transmitted to Towne Pediatric, but to another practice (ie an outpatient surgical center at which pediatrician has no affiliation).

Complainant is concerned that needed lab test results are not being delivered to the pediatric practice.

Category: Pre-Analytic

Sub-category: Specimen Handling

Details: Specimens are labelled at collection with an incorrect ID number. The results then are not sent to the ordering physician.

DEEMED/RO APPROVAL INFORMATION:

Ro Request for Approval: 06/19/2008

RO Disapproval Date: 06/26/2008

END OF INTAKE INFORMATION

Printed: 06/23/2010
Due Date: 08/09/2009
Priority: Non-IJ

INTAKE INFORMATION

Intake Number: VA00016624
Facility ID: VA22001516
Provider Number: 49D0231664
State Region: LAB

FACILITY INFORMATION:

Name: MONTGOMERY REGIONAL HOSPITAL
Address: 3700 S MAIN ST
City/State/Zip/County: BLACKSBURG, VA, 24060, MONTGOMERY
Telephone: (703) 951-1111

License #: _____
Type: LAB-ACCR
Administrator: _____

CAP

INTAKE INFORMATION:

Intake Number: VA00016624
Taken by - Staff: ARENDASH, ERIC
Location Received: COMPLAINT UNIT
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
CBER #: _____
SA Contact: BAGLEY, BRENDA
RO Contact: ARENDASH, ERIC
Responsible Team: _____
Source: Former Staff

Received Start: 06/25/2009 At 10:11
Received End: 06/25/2009 At 11:11
Received by: E-Mail
State Complaint ID: _____
CIS Number: _____
External Control #: _____
Certificate at Time of Alleged Event: Accreditation

CAP

COMPLAINANTS:

<u>Name</u>	<u>Address</u>	<u>Work Phone</u>	<u>Home Phone</u>	<u>Cell Phone</u>
(b)(6), (b)(7)c, (b)(7)d				

Confidentiality Requested: Y Link ID: (b)(6), (b)(7)c, (b)(7)d

INTAKE DETAIL:

Date of Alleged Event: _____ Time: _____ Shift: _____
Standard Notes: 1/14/10 OLC was not notified of this complaint. It was approved in June 2009. Eric Arendash of RO has directed OLC to move forward with investigation of complaint at this time.

(b)(6), (b)(7)c, (b)(7)d

Printed: 09/23/2010
Due Date: 08/09/2009
Priority: Non-IJ

INTAKE INFORMATION

Intake Number: VA00016624
Facility ID: VA22001516
Provider Number: 49D0231664
State Region: LAB

(b)(6), (b)(7)c, (b)(7)d

Extended RO Notes:

Extended CO Notes:

ALLEGATIONS:

Category: Facility Administration/Physical Environment

Sub-category:

Details: The following complaint regarding this facility was emailed to the Philly RO - CLIA Program from CO on 6/25/09. Complainant has sent identical email to numerous federal/state and private agencies/organizations that would have potential interest in this situation. Photos received from the complainant are attached.
June 19, 2009

(b)(6), (b)(7)c, (b)(7)d

Printed: 09/23/2010

Due Date:

Priority: No Action Necessary

INTAKE INFORMATION

Intake Number: VA00010145

Facility ID: VA22001177

Provider Number: 49D0897505

State Region: 001

FACILITY INFORMATION:

Name: PIEDMONT PEDIATRICS, INC

Address: 140 PINEY FOREST ROAD SUITE B

City/State/Zip/County: DANVILLE, VA, 24541, DANVILLE CITY

Telephone: (434) 793-7745

License #:

Type: LAB-PEND

Administrator:

INTAKE INFORMATION:

Intake Number: VA00010145

Taken by - Staff: BAGLEY, BRENDA

Location Received:

Intake Type: Complaint

Intake Subtype: No State or Federal provider compliance issue

CBER #:

SA Contact: CARDEN, KATHRYN A.

RO Contact:

Responsible Team: ACUTE CARE

Source: Family

Received Start: 08/31/2006 At 08:19

Received End: 08/31/2006 At 08:19

Received by: Telephone

State Complaint ID:

CIS Number:

External Control #:

Certificate at Time of Alleged Event: Compliance

No AD

COMPLAINANTS:

Name	Address	Work Phone	Home Phone	Cell Phone
	(b)(6), (b)(7)c			
Confidentiality Requested : N			Link ID: 06SHCR	

RESIDENTS/PATIENTS/CLIENTS:

Name	Admitted	Location	Discharged	Room	Link ID
		(b)(6), (b)(7)c			

INTAKE DETAIL:

Date of Alleged Event: Time: Shift:

Standard Notes: Complainant is the (b)(6), (b)(7)c Patient is a (b)(6), (b)(7)c who had a (b)(6), (b)(7)c

Extended RO Notes:

Extended CO Notes:

ALLEGATIONS:

Category: General

Sub-category: Other

Details: Complainant said that (b)(6), (b)(7)c had a sample of the (b)(6), (b)(7)c office in May 2006. The sample was sent to Carilion Consided Lab in Roanoke. Complainant has called the (b)(6), (b)(7)c repeatedly for the results of the test. This has not been provided to (b)(6), (b)(7)c by the (b)(6), (b)(7)c

Complainant said that on 8/26/06, (b)(6), (b)(7)c was informed via telephone that the sample had been sent to the State of Virginia lab because mold was growing on the sample.

Complainant said that (b)(6), (b)(7)c received the results on 8/30/06 from the (b)(6), (b)(7)c where (b)(6), (b)(7)c is currently being treated. Complainant said that (b)(6), (b)(7)c believes that the (b)(6), (b)(7)c received the test results in June 2006 and failed to notify (b)(6), (b)(7)c

END OF INTAKE INFORMATION

Printed: 09/23/2010
Due Date: 04/14/2009
Priority: Non-IJ

Intake Number: VA00015720
Facility ID: VA22002334
Provider Number: 49D0943753
State Region: 001

INTAKE NOTES

PROVIDER INFORMATION:

Name: PLANNED PARENTHOOD OF METROPOLITAN
Address: 370 S WASHINGTON STREET - SUITE 300
City/State/Zip/County: FALLS CHURCH, VA, 22046, FALLS CHURCH CITY
Telephone: (703) 533-5656

License #:
Type: LAB-CMPL
Medicaid #:
Administrator:

No AO

Intake Number: VA00015720
Intake Type: Complaint

Received Start Date: 02/09/09 At 14:33
Received End Date: 02/09/09 At 14:33

Standard Notes:

Complaint is the (b)(6), (b)(7)c (b)(6), (b)(7)c submitted a written complaint (attached) and also was interviewed by telephone on 2/9/09. The complainant is very concerned about the (b)(6), (b)(7)c (b)(6), (b)(7)c results that were reported for a 7/7/08 specimen obtained. According to two separate retests on 7/12/08 and 7/18/08 by two different physicians, the results reported by Planned Parenthood were inaccurate for this patient. Planned Parenthood has refused to correct the medical record to show the error. As well, the complainant is concerned that the results reported to (b)(6), (b)(7)c but belonging to another patient, may put this other patient and (b)(6), (b)(7)c contacts at risk because the other patient doesn't know the results were (b)(6), (b)(7)c .

SEE ATTACHED WRITTEN COMPLAINT AND LAB RESULTS (3) FOR DETAILS. Note: LabCorp in Herndon processed/analyzed the specimen that was collected at Planned Parenthood.

4/21/09 Letter to lab regarding deficiency and requesting POC is attached.

Extended RO Notes:

Printed: 09/23/2010
Due Date:
Priority: No Action Necessary

Intake Number: VA00016801
Facility ID: VA22001407
Provider Number: 49D1046110
State Region: LAB

INTAKE NOTES

PROVIDER INFORMATION:

Name: PLASMACARE, INC
Address: 117 S 3RD STREET
City/State/Zip/County: RICHMOND, VA, 23219, RICHMOND CITY
Telephone: (804) 643-6789

License #:
Type: LAB-CMPL
Medical #:
Administrator:

No AD

Intake Number: VA00016801
Intake Type: Complaint

Received Start Date: 07/21/09 At 08:20
Received End Date: 07/31/09 At 08:20

Standard Notes:

Complainant said that (b)(6), (b)(7)c has been donating plasma for approximately three months (b)(6), (b)(7)c said that on June 16, 2009 (b)(6), (b)(7)c donated plasma and (b)(6), (b)(7)c by home (b)(6), (b)(7)c became swollen and painful (b)(6), (b)(7)c spoke with someone at the lab the next day who told (b)(6), (b)(7)c that the blood had probably infiltrated causing the swelling and discoloration. (b)(6), (b)(7)c also spoke with a (b)(6), (b)(7)c (last name not known) (b)(6), (b)(7)c told (b)(6), (b)(7)c that someone should have told (b)(6), (b)(7)c what to expect and that infiltrations are not uncommon.

I asked (b)(6), (b)(7)c if when (b)(6), (b)(7)c began donating plasma (b)(6), (b)(7)c was given any information regarding the procedure and possible complications. (b)(6), (b)(7)c said that (b)(6), (b)(7)c may have but could not remember.

Informed (b)(6), (b)(7)c that (b)(6), (b)(7)c concern does not fall within the regulatory jurisdiction of OLC.

Extended RO Notes:

Printed: 09/23/2010
Due Date: 08/05/2006
Priority: Non-IJ

INTAKE INFORMATION

Intake Number: VA00009785
Facility ID: VA22003865
Provider Number: 49D0679652
State Region: LAB

FACILITY INFORMATION:

Name: PRIMARY HEALTH GROUP PC
Address: 6439 IRONBRIDGE ROAD
City/State/Zip/County: RICHMOND, VA, 23234, CHESTERFIELD
Telephone: (804) 271-8990

License #:
Type: LAB-ACCR
Administrator:

COLA

INTAKE INFORMATION:

Intake Number: VA00009785
Taken by - Staff: ARENDASH, ERIC
Location Received: ACUTE CARE
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
CBER #:
SA Contact: MORRIS, PHYLLIS
CARDEN, KATHRYN A.
RO Contact: ARENDASH, ERIC
Responsible Team: ACUTE CARE
Source: Current Staff
Former Staff

Received Start: 06/14/2006 At 09:35
Received End: 06/21/2006 At 08:54
Received by: E-Mail
State Complaint ID:
CIS Number:
External Control #:
Certificate at Time of Alleged Event: Accreditation

COLA

COMPLAINANTS:

Name	Address	Work Phone	Home Phone	Cell Phone
Not Applicable				
(b)(6), (b)(7)c, (b)(7)d	<u>Confidentiality Requested:</u> Y		<u>Link ID:</u> (b)(6), (b)(7)c, (b)(7)d	
	<u>Confidentiality Requested:</u> Y		(b)(6), (b)(7)c, (b)(7)d	
			<u>Link ID:</u> (b)(6), (b)(7)c, (b)(7)d	

INTAKE DETAIL:

Date of Alleged Event: Time: Shift:
Standard Notes: Complaint received by the RO. Complainant wishes to remain anonymous.

7/18/06 Spoke with complainant (b)(6), (b)(7)c, (b)(7)d. Complainant did not want a follow up letter with survey results. (b)(6), (b)(7)c, (b)(7)d had heard that the inspector said everything is "all right" and I know it's not so I don't need the letter.

Extended RO Notes: Complainant is (b)(6), (b)(7)c, (b)(7)d

Complainant further stated that (b)(6), (b)(7)c, (b)(7)d expressed concern with CLIA compliance and was told not to worry. I will contact (b)(6), (b)(7)c, (b)(7)d to get further details on this issue with CLIA group in VA SA if that (b)(6), (b)(7)c, (b)(7)d spoke with.

Contacted (b)(6), (b)(7)c, (b)(7)d on 6/21/06 @ 09:30 by phone and clarified that CLIA Compliance WAS NOT the VA SA CLIA program, but the practice's CLIA Compliance office out of HCA Healthcare System and by the (b)(6), (b)(7)c (b)(6), (b)(7)c

Extended CO Notes:

ALLEGATIONS:

Category: General Lab Systems
Sub-category: Other
Details:

There is no current procedures written to guide employees who step in to perform testing in the laboratory.

Category: Analytic
Sub-category: Other

Details: Employees in the practice are being asked to perform laboratory procedures they feel are beyond their competency levels.

Category: General
Sub-category: Unqualified Personnel
Details:

Moderate complex procedures are being performed by non-credentialed staff.

Printed: 09/23/2010

Due Date:

Priority: No Action Necessary

INTAKE INFORMATION

Intake Number: VA00017764

Facility ID: VA22003278

Provider Number: 49D0221801

State Region: LAB

FACILITY INFORMATION:

Name: QUEST DIAGNOSTICS NICHOLS INSTITUTE

Address: 14225 NEWBROOK DRIVE

City/State/Zip/County: CHANTILLY, VA, 20151, FAIRFAX

Telephone: (703) 691-9100

License #:

Type: LAB-ACCR

Administrator:

CAP

INTAKE INFORMATION:

Intake Number: VA00017764

Taken by - Staff: KING, ELIZABETH

Location Received:

Intake Type: Complaint

Intake Subtype: No State or Federal provider compliance issue

CBER #:

SA Contact: JONES, TC

RO Contact: ARENDASH, ERIC

Responsible Team: ACUTE CARE

Source: Resident/Patient/Client

Received Start: 01/05/2010 At 15:25

Received End: 01/05/2010 At 15:25

Received by: Written

State Complaint ID:

CIS Number:

External Control #:

Certificate at Time of Alleged Event: Accreditation

CAP

COMPLAINANTS:

Name	Address	Work Phone	Home Phone	Cell Phone
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(b)(6), (b)(7)c, (b)(7)d

Confidentiality Requested: Y

Link ID: (b)(6), (b)(7)c, (b)(7)d

INTAKE DETAIL:

Date of Alleged Event: Time: Shift:

Standard Notes: Complainant(s) (b)(6), (b)(7)c, (b)(7)d had an unduced sputum done and then received the results from Quest Laboratory where the specimen was sent for analysis. The specimen was an (b)(6), (b)(7)c, (b)(7)d was (b)(6), (b)(7)c, (b)(7)d and this was reported on 4/20/2009.

Complainant is concerned that the lab reported a (b)(6), (b)(7)c, (b)(7)d to the State of Pennsylvania Health Department (b)(6), (b)(7)c, (b)(7)d was (b)(6), (b)(7)c, (b)(7)d with a diagnosis of tuberculosis, especially for a healthcare provider."

Complaint scanned and sent to Eric Arendash at the RO for review and no CLIA issues found.

** No action necessary**

Extended RO Notes:

Extended CO Notes:

ALLEGATIONS:

Category:

Sub-category:

Details:

DEEMED/RO APPROVAL INFORMATION:

Ro Request for Approval: 01/05/2010

RO Disapproval Date: 01/05/2010

END OF INTAKE INFORMATION

INTAKE INFORMATION

FACILITY INFORMATION:

Name: SENTARA FAMILY MEDICINE AND URGENT CARE PC
 Address: 816 INDEPENDENCE BOULEVARD - SUITE 100
 City/State/Zip/County: VIRGINIA BEACH, VA, 23455, VIRGINIA BEACH CIT
 Telephone: (757) 363-6812

License #:
 Type: LAB-CMPL
 Administrator:

INTAKE INFORMATION:

Intake Number: VA00009514
 Taken by - Staff: WAWNER, ELEANOR
 Location Received:
 Intake Type: Complaint
 Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
 CBER #:
 SA Contact: LONG, DONALD
 RO Contact:
 Responsible Team: ACUTE CARE
 Source: Resident/Patient/Client

Received Start: 04/24/2006 At 13:53
 Received End: 04/24/2006 At 13:53
 Received by: Hotline
 State Complaint ID:
 CIS Number:
 External Control #:
 Certificate at Time of Alleged Event: Compliance

No AD

COMPLAINANTS:

Name	Address	Work Phone	Home Phone	Cell Phone
	(b)(6), (b)(7)c			
	<u>Confidentiality Requested</u> : N		<u>Link ID</u> : (b)(6), (b)(7)c	

RESIDENTS/PATIENTS/CLIENTS:

Name	Admitted	Location	Discharged	Room	Link ID
		(b)(6), (b)(7)c			

INTAKE DETAIL:

Date of Alleged Event: 04/19/2006 Time: Shift:

Standard Notes: The complainant reported that (b)(6), (b)(7)c had an appointment on 4/19/06 at 2:30 PM for blood work to be drawn. (b)(6), (b)(7)c would not draw the blood and told the complainant that they did not have the necessary tubes. The complainant was told (b)(6), (b)(7)c would have to go to the hospital's lab to have the test drawn, however when (b)(6), (b)(7)c complained about this to a (b)(6), (b)(7)c a second lab tech was able to draw the blood without problem.

The (b)(6), (b)(7)c who would not draw the blood was also identified to the complainant as a (b)(6), (b)(7)c

The complainant believes the (b)(6), (b)(7)c did not want to draw (b)(6), (b)(7)c blood because (b)(6), (b)(7)c was recently (b)(6), (b)(7)c. The complainant reported since the 4/19/06 event, the entire office knows about (b)(6), (b)(7)c diagnosis.

(b)(6), (b)(7)c who would not draw the blood was named (b)(6), (b)(7)c. The complainant did not know (b)(6), (b)(7)c first name.

5/10/06 Non-regulatory letter to complainant and HIPPA instructions and complaint form sent.

Extended RO Notes: This is not a CLIA matter. CLIA is not involved in the drawing of blood (only in the performance of laboratory tests). The complainant seems to have a legitimate HIPAA complaint, regarding the sharing of confidential medical information. Have the complainant go to www.hhs.gov/ocr. That is the site for the Office of Civil Rights, which oversees HIPAA complaints. There is a form on that site which can be filled out by a complainant.

Extended CO Notes:

ALLEGATIONS:

Category: General Lab Systems
 Sub-category: Other

Details: The complainant reported that (b)(6), (b)(7)c had an appointment on 4/19/06 at 2:30 PM for blood work to be drawn. The (b)(6), (b)(7)c would not draw the blood and told the complainant that they did not have the necessary tubes. The complainant was told (b)(6), (b)(7)c would have to go to the hospital's lab to have the test drawn, however when (b)(6), (b)(7)c complained about this to a supervisor, a second (b)(6), (b)(7)c was able to draw the blood without problem.

The (b)(6), (b)(7)c who would not draw the blood was also identified to the complainant as a (b)(6), (b)(7)c

Printed: 09/23/2010
Due Date: 04/30/2010
Priority: Non-IJ

INTAKE INFORMATION

Intake Number: VA00018147
Facility ID: VA22011027
Provider Number: 49D1096052
State Region: LAB

FACILITY INFORMATION:

Name: SKIN LASER SURGERY CENTER, PC
Address: 8130 BOONE BOULEVARD - SUITE 340
City/State/Zip/County: VIENNA, VA, 22182, FAIRFAX
Telephone: (703) 893-1114

License #:
Type: LAB-CMPL
Administrator:

INTAKE INFORMATION:

Intake Number: VA00018147
Taken by - Staff: ARENDASH, ERIC
Location Received: COMPLAINT UNIT
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
CBER #:
SA Contact: BAGLEY, BRENDA
RO Contact: ARENDASH, ERIC
Responsible Team: ACUTE CARE
Source: Anonymous
CMS

Received Start: 03/16/2010 At 13:30
Received End: 03/16/2010 At 14:10
Received by:
State Complaint ID:
CIS Number:
External Control #:
Certificate at Time
of Alleged Event: Registration (Compliance)

No AO

COMPLAINANTS:

<u>Name</u>	<u>Address</u>	<u>Work Phone</u>	<u>Home Phone</u>	<u>Cell Phone</u>
Not Applicable				
<u>Confidentiality Requested</u> : Y				<u>Link ID</u> : (b)(6), (b)(7)c

INTAKE DETAIL:

Date of Alleged Event: Time: Shift:
Standard Notes: CLIA Complaint received from the OIG HOTLINE as case # L111557 back in September 2, 2009. 3/11/10 case was referred from CMS to Regional Office - Philadelphia to address allegations of CLIA violations. See Attachment for details on alleged violations.
Extended RO Notes:
Extended CO Notes:

ALLEGATIONS:

Category: Analytic
Sub-category: Other
Details: Please review for any CLIA testing being done at the office located at:

Skin & Laser Surgery Center
Tompkins-Martin Medical Plaza
1101 Sam Perry Boulevard
Suite 314
Fredericksburg, VA 22401

Also please review the complainant's written complaint for any CLIA issues I may not be aware of! Brenda

Category: General
Sub-category: Unqualified Personnel

Details: Complainant stated that (b)(7)c, (b)(7)d that are processing tissues from Mohs procedures do not have the required level of education.

(b)(7)c, (b)(7)d practice does not have (b)(6), (b)(7)c, (b)(7)d to process the slides. The practice does not have personnel that are properly trained to operate the Cryostat machine, evaluate equipment or keep proper records.

SURVEY INFORMATION:

<u>Event ID</u>	<u>Start Date</u>	<u>Exit Date</u>	<u>Team Members</u>
PS1Z11	04/29/10	04/29/10	LOGAN, CHEVONNE DURISH, LISA

Printed: 09/23/2010
Due Date: 07/21/2008
Priority: Non-IJ

INTAKE INFORMATION

Intake Number: VA00014431
Facility ID: VA22003929
Provider Number: 49D0686045
State Region: LAB

FACILITY INFORMATION:

Name: SOUTHSIDE COMMUNITY HOSPITAL
Address: 800 OAK ST
City/State/Zip/County: FARMVILLE, VA, 23901, PRINCE EDWARD
Telephone: (434) 315-2831

License #:
Type: LAB-ACCR
Administrator: *Joint Commission*

INTAKE INFORMATION:

Intake Number: VA00014431
Taken by - Staff: SNYDER, BENJAMIN
Location Received: ACUTE CARE
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
CBER #: 08-047
SA Contact:
RO Contact:
Responsible Team: ACUTE CARE
Source: Current Staff
FDA

Received Start: 06/05/2008 At 10:59
Received End: 06/05/2008 At 10:59
Received by: E-Mail
State Complaint ID:
CIS Number:
External Control #:
Certificate at Time of Alleged Event: Accreditation
JL

COMPLAINANTS:

Name	Address	Work Phone	Home Phone	Cell Phone
	(b)(6), (b)(7)c, (b)(7)d			
	<u>Confidentiality Requested:</u> Y		<u>Link ID:</u> (b)(6), (b)(7)c, (b)(7)d	

RESIDENTS/PATIENTS/CLIENTS:

Name	Admitted	Location	Discharged	Room	Link ID
		(b)(6), (b)(7)c, (b)(7)d			

INTAKE DETAIL:

Date of Alleged Event: Time: Shift:
Standard Notes: A (b)(6), (b)(7)c, (b)(7)d patient, who was (b)(6), (b)(7)c, (b)(7)d was administered one unit of (b)(6), (b)(7)c, (b)(7)d . The transfusion occurred on 4/30/2008 in the E.R., and the patient died on 5/2/2008. The hospital states that the error was the fault of (b)(6), (b)(7)c, (b)(7)d

9/19/08 CMS condition level deficiency letter to lab is attached.

Extended RO Notes:

Extended CO Notes:

ALLEGATIONS:

Category: Pre-Analytic

Sub-category: Other

Details: A (b)(6), (b)(7)c, (b)(7)d , who was (b)(6), (b)(7)c, (b)(7)d was administered one unit of (b)(6), (b)(7)c, (b)(7)d . The transfusion occurred on 4/30/2008 in the E.R., and the patient died on 5/2/2008. The hospital states that the error was the fault of (b)(6), (b)(7)c, (b)(7)d

CONTACTS:

NASH, H. ROBERT
SOUTHSIDE COMMUNITY HOSPITAL
FARMVILLE, VA 23901

Blood Bank Director
(434)315-2616

DEEMED/RO APPROVAL INFORMATION:

Ro Request for Approval: RO Approval Date: 06/05/2008

SURVEY INFORMATION:

Event ID	Start Date	Exit Date	Team Members
N37U11	07/14/08	07/17/08	BALLAS, KAY LOGAN, CHEVONNE

Printed: 09/23/2010
Due Date: 03/06/2009
Priority: Non-IJ

INTAKE INFORMATION

Intake Number: VA00015523
Facility ID: VA22001898
Provider Number: 49D0222887
State Region: 001

FACILITY INFORMATION:

Name: UNITED MEDICAL LABS INC
Address: 7601 LEWINSVILLE ROAD - SUITE 300
City/State/Zip/County: MC LEAN, VA, 22102, FAIRFAX
Telephone: (703) 356-4422

License #:
Type: LAB-CMPL
Administrator:

INTAKE INFORMATION:

Intake Number: VA00015523
Taken by - Staff: ARENDASH, ERIC
Location Received:
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
CBER #:
SA Contact: BEAZLEY, KIMBERLY
 BAGLEY, BRENDA
RO Contact: ARENDASH, ERIC
Responsible Team:
Source: State Survey Agency

Received Start: 12/30/2008 At 08:18
Received End: 12/30/2008 At 11:18
Received by: E-Mail
State Complaint ID:
CIS Number:
External Control #:
Certificate at Time
of Alleged Event: Compliance *No AO*

COMPLAINANTS:

<u>Name</u>	<u>Address</u>	<u>Work Phone</u>	<u>Home Phone</u>	<u>Cell Phone</u>
	(b)(6), (b)(7)c, (b)(7)d			
	<u>Confidentiality Requested</u> : Y		<u>Link ID</u> (b)(6), (b)(7)c, (b)(7)d	

INTAKE DETAIL:

Date of Alleged Event: Time: Shift:
Standard Notes:

(b)(6), (b)(7)c, (b)(7)d

7/30/09 POC is attached.

Extended RO Notes:
Extended CO Notes:

ALLEGATIONS:

Category: Post-Analytic
Sub-category: Other

Details: To VA SA: Please conduct a CLIA complaint investigation of (b)(6), (b)(7)c (United Medical Labs) asap to determine if the alleged provider signed out any Cytologic preparations after failing the 2nd Retest dated May 30, 2007.

SURVEY INFORMATION:

<u>Event ID</u>	<u>Start Date</u>	<u>Exit Date</u>	<u>Team Members</u>
P93Z11	02/09/09	04/03/09	BALLAS, KAY LOGAN, CHEVONNE

EXCL (31)

Printed: 09/23/2010

Due Date:

Priority: No Action Necessary

INTAKE INFORMATION

Intake Number: VA00017379

Facility ID: VA22002253

Provider Number: 49D1032785

State Region: LAB

FACILITY INFORMATION:

Name: VCU HEALTH SYSTEM AUTHORITY - MCV HOSPITAL:

Address: 1201 E MARSHALL STREET

City/State/Zip/County: RICHMOND, VA, 23221, RICHMOND CITY

Telephone: (804) 828-7953

License #:

Type: LAB-ACCR

Administrator:

CAP

INTAKE INFORMATION:

Intake Number: VA00017379

Taken by - Staff: BAGLEY, BRENDA

Location Received:

Intake Type: Complaint

Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA

CBER #:

SA Contact: JONES, TC

RO Contact:

Responsible Team: ACUTE CARE

Source: Resident/Patient/Client

Received Start: 11/03/2009 At 08:14

Received End: 11/03/2009 At 08:14

Received by: Written

State Complaint ID:

CIS Number:

External Control #:

Certificate at Time of Alleged Event: Registration (Accreditation)

CAP

COMPLAINANTS:

Name	Address	Work Phone	Home Phone	Cell Phone
	(b)(6), (b)(7)c, (b)(7)d			
	<u>Confidentiality Requested</u> : Y		<u>Link ID</u> : (b)(6), (b)(7)c, (b)(7)d	

RESIDENTS/PATIENTS/CLIENTS:

Name	Admitted	Location	Discharged	Room	Link ID
		(b)(6), (b)(7)c, (b)(7)d			

INTAKE DETAIL:

Date of Alleged Event: Time: Shift:

Standard Notes: On 10/14/09 received copy of email to the governor from (b)(6), (b)(7)c, (b)(7)d who asked the governor to assist (b)(6), (b)(7)c, (b)(7)d in bringing some action against VCU (b)(6), (b)(7)c, (b)(7)d. (b)(6), (b)(7)c, (b)(7)d said that (b)(6), (b)(7)c, (b)(7)d had a paternity test at VCU in 2003 that was a false negative. (b)(6), (b)(7)c, (b)(7)d recently had a repeat paternity test and (b)(6), (b)(7)c, (b)(7)d has learned that (b)(6), (b)(7)c, (b)(7)d is the father of the child.

Spoke with Ben Snyder at (b)(6), (b)(7)c, (b)(7)d and he said that this type of testing does not fall under CLIA.

I called (b)(6), (b)(7)c, (b)(7)d on 10/21/09 and (b)(6), (b)(7)c, (b)(7)d is not regulated by CLIA. (b)(6), (b)(7)c, (b)(7)d gave (b)(6), (b)(7)c, (b)(7)d a toll free number and website address for the American College of Pathologists and (b)(6), (b)(7)c, (b)(7)d said that organization may investigate his concerns.

(b)(6), (b)(7)c, (b)(7)d email to the governor is attached.

Extended RO Notes:

Extended CO Notes:

ALLEGATIONS:

Category:

Sub-category:

Details:

DEEMED/RO APPROVAL INFORMATION:

Ro Request for Approval:

RO Approval Date:

END OF INTAKE INFORMATION

Printed: 09/23/2010
Due Date: 09/11/2007
Priority: Non-IJ

INTAKE INFORMATION

Intake Number: VA00011953
Facility ID: VA22000489
Provider Number: 49D0224076
State Region: LAB

FACILITY INFORMATION:

Name: VIRGINIA HOSPITAL CENTER ARLINGTON
Address: 1701 N GEORGE MASON DR
City/State/Zip/County: ARLINGTON, VA, 22205, ARLINGTON
Telephone: (703) 558-6551

License #:
Type: LAB-ACCR
Administrator: CAP

INTAKE INFORMATION:

Intake Number: VA00011953
Taken by - Staff: HANK, SALLY
Location Received:
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
CBER #:
SA Contact: STOLCIS, GREG
RO Contact: ARENDASH, ERIC
Responsible Team: ACUTE CARE
Source: Resident/Patient/Client

Received Start: 06/25/2007 At 11:26
Received End: 07/09/2007 At 11:26
Received by: Hotline
State Complaint ID:
CIS Number:
External Control #:
Certificate at Time of Alleged Event: Accreditation
CAP

COMPLAINANTS:

Name	Address	Work Phone	Home Phone	Cell Phone
	(b)(6), (b)(7)c, (b)(7)d			
<u>Confidentiality Requested:</u> Y				<u>Link ID:</u> (b)(6), (b)(7)c, (b)(7)d

RESIDENTS/PATIENTS/CLIENTS:

Name	Admitted	Location	Discharged	Room	Link ID
		(b)(6), (b)(7)c, (b)(7)d			

INTAKE DETAIL:

Date of Alleged Event: Time: Shift:

Standard Notes: Complainant received care in the hospital ED on 6/6-7/07. Two problems with the handling of laboratory tests occurred during this time.

6/26/07 Received by Fax a written account of the complaint from the complainant (attached). SH

7/9/07 Received call from the complainant requesting status report. (b)(6), (b)(7)c, (b)(7)d called the administration of the hospital and the Patient Relations office regarding (b)(6), (b)(7)c, (b)(7)d and the need to verify that (b)(6), (b)(7)c, (b)(7)d is no longer listed with the public health department in Arlington as being a contact for (b)(6), (b)(7)c, (b)(7)d. (b)(6), (b)(7)c, (b)(7)d had no return call as promised from these sources, nor from the local health department.

Extended RO Notes:

Extended CO Notes:

ALLEGATIONS:

Category: Pre-Analytic

Sub-category: Specimen Handling

Details: Patient was admitted to the ED at approximately 7:30 p.m. on 6/6/07. Chief complaints: severe (b)(6), (b)(7)c and pain. Blood was drawn soon after arrival. Early in the a.m. of 6/7/07, an ED nurse advised patient that the blood drawn earlier had been lost and a second draw was needed; this second specimen was collected. The patient remained under observation in the ED following a CT scan until 6:45 a.m. on 6/7/07 (b)(6), (b)(7)c, (b)(7)d discharged home with a prescription for the treatment of a (b)(6), (b)(7)c, (b)(7)d and instructions to follow up with (b)(6), (b)(7)c family doctor. The patient's attending ED physician was (b)(6), (b)(7)c, (b)(7)d

On 6/8/07, at approximately 5:30 p.m., the patient received a phone call from the hospital ED advising (b)(6), (b)(7)c, (b)(7)d to stop taking the medication prescribed and to return to the ED at once because (b)(6), (b)(7)c was (b)(6), (b)(7)c. The patient told the caller that this was impossible and to file a (b)(6), (b)(7)c report. The report was faxed -- the report showed (b)(6), (b)(7)c, (b)(7)d as the patient but neither of the two physicians named on the report had (b)(6), (b)(7)c with in the ED. The physicians named were (b)(6), (b)(7)c. The patient returned to the ED and was seen by (b)(6), (b)(7)c. A test (b)(6), (b)(7)c, (b)(7)d was conducted with negative findings. As reported (b)(6), (b)(7)c, (b)(7)d stated (b)(6), (b)(7)c couldn't believe this kind of a mix up could occur. The patient was troubled about the mix up but also upset about

Printed: 09/23/2010
Due Date: 10/21/2008
Priority: Non-IJ

INTAKE INFORMATION

Intake Number: VA00014799
Facility ID: VA22005466
Provider Number: 49D0225083
State Region: 001

FACILITY INFORMATION:

Name: WHITE STONE FAMILY PRACTICE PC
Address: 30 SHADY LANE
City/State/Zip/County: WHITE STONE, VA, 22578, LANCASTER
Telephone: (804) 435-3133

License #:
Type: LAB-CMPL
Administrator:

INTAKE INFORMATION:

Intake Number: VA00014799
Taken by - Staff: HANK, SALLY
Location Received:
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
CBER #:
SA Contact: BEAZLEY, KIMBERLY
RO Contact:
Responsible Team: ACUTE CARE
Source: Anonymous

Received Start: 08/15/2008 At 14:22
Received End: 08/15/2008 At 14:22
Received by: Telephone
State Complaint ID:
CIS Number:
External Control #:
Certificate at Time of Alleged Event: Compliance

~~AD~~ AD
No

COMPLAINANTS:

<u>Name</u>	<u>Address</u>	<u>Work Phone</u>	<u>Home Phone</u>	<u>Cell Phone</u>
Not Applicable				

Confidentiality Requested : Y Link ID (b)(6), (b)(7)c, (b)(7)d

INTAKE DETAIL:

Date of Alleged Event: Time: Shift:
Standard Notes: Anonymous complainant.
Extended RO Notes:
Extended CO Notes:

ALLEGATIONS:

Category: Analytic
Sub-category: Other
Details: Allegation: Personnel conducting analysis by (b)(6), (b)(7)c are not trained.
The lab personnel who were trained to do the (b)(6), (b)(7)c have left the facility. Currently, the analysis is being run by (b)(6), (b)(7)c who have no training.

SURVEY INFORMATION:

<u>Event ID</u>	<u>Start Date</u>	<u>Exit Date</u>	<u>Team Members</u>
5UNR11	09/18/08	09/18/08	LOGAN, CHEVONNE

ACTIVITIES:

<u>Type</u>	<u>Sent</u>	<u>Due</u>	<u>Completed</u>	<u>Responsible Staff Member</u>
Schedule Onsite Visit	09/18/2008	09/18/2008	09/18/2008	LOGAN, CHEVONNE

END OF INTAKE INFORMATION

Printed: 09/23/2010
Due Date:
Priority: No Action Necessary

INTAKE INFORMATION

Intake Number: VA00010060
Facility ID: VA22004064
Provider Number: 49D1048957
State Region: LAB

FACILITY INFORMATION:

Name: WILLIAM M HANDY, MD, FAAFP
Address: 389 FALLS DRIVE
City/State/Zip/County: ABINGDON, VA, 24210, WASHINGTON
Telephone: (276) 623-0740

License #:
Type: LAB-WAIV
Administrator:

INTAKE INFORMATION:

Intake Number: VA00010060
Taken by - Staff: BUCHANAN, LEONARD E.
Location Received: COMPLAINT UNIT
Intake Type: Complaint
Intake Subtype: Federal COPs, CFCs, RFPs, EMTALA, CLIA
CBER #:
SA Contact: CARDEN, KATHRYN A.
RO Contact:
Responsible Team: ACUTE CARE
Source: Resident/Patient/Client

Received Start: 08/10/2006 At 14:24
Received End: 08/10/2006 At 14:24
Received by: Written
State Complaint ID:
CIS Number:
External Control #:
Certificate at Time of Alleged Event: Waiver *No AO*

COMPLAINANTS:

<u>Name</u>	<u>Address</u>	<u>Work Phone</u>	<u>Home Phone</u>	<u>Cell Phone</u>
	(b)(6), (b)(7)c, (b)(7)d			

Confidentiality Requested: Y Link ID: (b)(6), (b)(7)c, (b)(7)d

RESIDENTS/PATIENTS/CLIENTS:

<u>Name</u>	<u>Admitted</u>	<u>Location</u>	<u>Discharged</u>	<u>Room</u>	<u>Link ID</u>
		(b)(6), (b)(7)c			

INTAKE DETAIL:

Date of Alleged Event: Time: Shift:
Standard Notes: Reviewed with CLIA inspector Non of the concerns are regulatory Willreccomend that the complainant contact OSHA
Extended RO Notes:
Extended CO Notes:

ALLEGATIONS:

Category:
Sub-category:
Details:

DEEMED/RO APPROVAL INFORMATION:

Ro Request for Approval: RO Approval Date:

END OF INTAKE INFORMATION

(b)(6), (b)(7)c, (b)(7)d'

August 4, 2006

VA Dept of Health
Center for Quality Health Care Services
3600 W. Broad St.
Suite 216
Richmond, VA 23230

RECEIVED
VDH/OLC

ATTN: (b)(6), (b)(7)c

Dear Ms Pendergrass:

I am writing to inform you of the following possible CLIA violations and hazards in the office of Dr. William Handy located at 389 Falls Plaza in Abingdon, Virginia as of mid-April.

- 1. (b)(6), (b)(7)c ; working in the back office and lab area barefoot and also without shoes at times. (Witnessed by patients and other staff.)
- 2. Personal Protective equipment not available to staff—no gowns and safety sharps not used; (b)(6), (b)(7)c advised we would order one box to keep incase of inspection.
3. Biohazard waste contaminated with blood and other bodily fluids thrown in regular garbage cans in patient exam rooms, by physician.
4. OSHA training not completed by trained (b)(6), (b)(7)c and in some cases not done at all.
5. Thermometer and Humidity Logs for lab and medication refrigerators not checked and documented daily.
6. Control Logs for lab equipment used to check urinalysis, pro-times, A1-c, and cholestech not being done daily and documented prior to use and not logged in patient logbook.
7. Eyewash not checked and documented weekly. (Weekly eyewash and BUMP test-in OSHA book)
8. No documentation of wet mounts, microscope urinalysis, and Rapid Strep tests or pregnancy tests in laboratory patient log books.
9. Narcotics not double locked and checked and documented daily. Narcotics box is located in patient sample closet but not locked with key and sample closet left open regularly in high patient pathway area.
10. Injections given without documenting log number and expiration date in injection logbook and also in some cases not even documented in patient charts by physician.
11. Overfilling of sharps containers.
12. Biohazard waste container in utility closet blocked by other boxes and supplies piled on top of the container.
13. Biohazard waste containers in rooms not changed regularly.

August 4, 2006

These things are of great concern to me, due to the fact (b)(6), (b)(7)c does not have staff (b)(6), (b)(7)c
are medically trained to document or perform the tasks listed above on a regular basis (b)(6), (b)(7)c
(b)(6), (b)(7)c and (b)(6), (b)(7)c administering
injections, giving breathing treatments to patients, giving patients medication samples and directions on
how to take the medicines, and calling in controlled medications to pharmacies and running some of
the above listed tests with no medical training or license. I am very concerned that these things create
a very hazardous environment for both patients and employees that visit that facility. Please feel free to
contact me regarding these allegations or more specific details at the address and/or phone numbers
listed at the top of this letter.

Sincerely,

(b)(6), (b)(7)c, (b)(7)d