

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0290593	<b>(X3) Date Survey Completed</b>  02/05/2018
<b>Name of Provider or Supplier</b>  Tampa Womens Health Center Inc	<b>Street Address, City, State</b>  2010 E Fletcher Ave, Tampa, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The Tampa Woman's Health Center clinical laboratory is not in compliance with the 42 CFR Part 493, Requirements for Laboratories. Biennial certification survey was conducted 02/02/18 thru 02/05/18. Based on the survey findings, an Immediate Jeopardy situation was identified and the laboratory was notified at 5:30 PM on 02/02/18. The laboratory failed to identify and correct problems in the subspecialties of ABO Group and Rh Group. The laboratory failed to document the room temperature and humidity every day of testing. The laboratory used expired reagents. The laboratory failed to document daily quality control. The laboratory failed to conduct quarterly quality assurance reviews to identify problems. The laboratory has been performing moderately complex ABO Group and Rh Type testing since August 1994 and has an annual testing volume of 1,700.
<b>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing and interview with Testing Person #A, the Laboratory Director failed to document the review of the proficiency testing for 3 (1st, 2nd, 3rd testing event in 2017) out of 6 (1st, 2nd, 3rd testing events in 2016 and 2017) testing events reviewed. Findings Included: Review of API proficiency testing for the 1st, 2nd, and 3rd testing event revealed that the Laboratory Director did not have documentation that the results were reviewed. During an interview on 02/02/17 at 4:00 PM Testing Person #A confirmed that there was no documentation of review.</p>
<b>D5400</b>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p>

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on observation, record review, and interview with Testing Person #A, the laboratory failed to record room temperatures and humidity (See D5413), used expired reagent (See D5417), failed to document daily quality control (See D5441), and failed to complete quarterly quality assurance (See D5791) in the subspecialty of ABO group and Rh group.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on record review and interview with Testing Person #A, the laboratory failed to record the room temperature (9 out of 539 days) and humidity (182 days out of 539 days). Findings Included: Review of "Daily Laboratory Log Sheet" revealed that for the period of 01/02/16 thru 02/01/18 that was reviewed, the laboratory failed to record the temperature and humidity in the room where testing was performed on 02/06/17, 01/26/17, 12/29/16, 12/27/16, 12/26/16, 07/18/16, 07/14/16, 05/02/16, and 03/04/16. The laboratory also failed to record the humidity in the room where testing was performed on 07/29/17, 02/28/17, 02/27/17, 02/09/17, 02/07/17, 02/03/17, 02/02/17, 01/14/17, 01/12/17, 01/08/17, 01/05/17, 01/03/17, 01/02/17, 12/31/16, 12/24/16, 12/23/16, 12/22/16, 12/20/16, 12/19/16, 12/17/16, 12/16/17, 12/15/16, 12/13/16, 12/12/16, 12/08/16, 12/09/16, 12/07/16, 12/05/16, 12/03/16, 12/02/16, 12/01/16, 11/29/16, 11/28/16, 11/25/16, 11/22/16, 11/21/16, 11/19/16, 11/18/16, 11/17/16, 11/16/16, 11/15/16, 11/14/16, 11/12/16, 11/11/16, 11/10/16, 11/07/16, 11/05/16, 11/04/16, 11/03/16, 11/01/16, 10/29/16, 10/28/16, 10/27/16, 10/25/16, 10/24/16, 10/22/16, 10/21/16, 10/20/16, 10/18/16, 10/17/16, 10/15/16, 10/14/16, 10/13/16, 10/11/16, 10/10/16, 10/08/16, 10/07/16, 10/06/16, 10/04/16, 10/01/16, 09/30/16, 09/29/16, 09/27/16, 09/26/17, 09/24/16, 09/23/16, 09/22/16, 09/20/16, 09/19/16, 09/17/16, 09/16/17, 09/15/16, 09/13/16, 09/12/16, 09/10/16, 09/09/16, 09/07/16, 09/06/16, 09/03/16, 09/02/16, 09/01/16, 08/30/16, 08/29/16, 08/27/16, 08/26/16, 08/25/16, 08/23/16, 08/22/16, 08/20/16, 08/18/16, 08/16/16, 08/15/16, 08/13/16, 08/12/16, 08/11/16, 08/09/16, 08/08/16, 08/06/16, 08/05/16/, 08/04/16, 08/02/16, 08/01/16, 07/31/16, 07/30/16, 07/29/16, 07/28/16, 07/26/16, 07/25/16, 07/23/16, 07/22/16, 07/21/16, 07/19/16, 07/16/16, 07/12/16, 07/11/16, 07/09/16, 07/08/16, 07/07/16, 07/05/16, 07/02/16, 06/30/16, 06/28/16, 06/27/16, 06/25/16, 06/24/16, 06/23/16, 06/21/16, 06/20/16, 05/10/16, 03/05/16, 03/03/16, 03/01/16, 02/29/16,

02/27/16, 02/26/17, 02/25/16, 02/23/16, 02/22/16, 02/20/16, 02/19/16, 02/18/16, 02/16/16, 02/15/16, 02/13/16, 02/12/16, 02/11/16, 02/09/16, 02/06/16, 02/05/16, 02/04/16, 02/02/16, 02/01/16, 01/31/16, 01/30/16, 01/29/16, 01/28/16, 01/26/16, 01/25/16, 01/23/16, 01/22/16, 01/21/16, 01/19/16, 01/18/16, 01/16/16, 01/15/16, 01/14/16, 01/12/16, 01/11/16, 01/09/16, 01/08/16, 01/07/16, 01/05/16, 01/04/16, and 01/02/16. During an interview on 02/02/18 at 4:04 PM Testing Person #A confirmed that the documentation of the room temperature and humidity were missing from the daily logs.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with Testing Person #A, the laboratory used expired reagent from 09/09/17 to 10/25/17. Findings Included: During a tour of the testing area on 02/02/18 at 2:30 PM a bottle of Anti-D Gamma-clone (Lot#350013 Expired 09/08/17) was in the laboratory refrigerator. Review of the "Daily Laboratory Log Sheet" revealed that the expired reagent was used from 09/09/17 to 10/25/17. The expired reagent was used for a total of 32 day to include 217 patients. During an interview on 02/02/18 at 2:30 PM Testing Person #A confirmed that the reagent used was expired.

**D5441**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview with Testing Person #A the laboratory failed to document the quality control (QC) every day of testing for 427 days out of 539 days reviewed. Findings Included: Review of "Daily Laboratory Log Sheet" revealed no documentation of a negative or positive control on 01/22/18 (10 patients), 01/20/18 (10 patients), 01/19/18 (12 patients), 01/18/18 (14 patients), 01/17/18 (14 patients), 01/15/18 (4 patients), 01/13/18 (12 patients), 01/12/18 (7 patients), 01/11/18 (8 patients), 01/10/18 (12 patients), 01/08/18 (8 patients), 01/06/18 (13 patients), 01/05/18 (14 patients), 01/04/18 (6 patients), 01/03/18 (11 patients), 12/30/17 (15 patients), 12/29/17 (12 patients), 12/28/17 (11 patients), 12/27/17 (14 patients), 12/26/17 (2 patients), 12/22/17 (8 patients), 12/21/17 (16 patients), 12/20/16 (6 patients), 12/18/17 (8

patients), 12/16/17 (7 patients), 12/15/17 (9 patients), 12/14/17 (12 patients), 12/13/17 (8 patients), 12/11/17 (6 patients), 12/09/17 (9 patients), 12/08/17 (9 patients), 12/07/17 (14 patients), 12/06/17 (10 patients), 12/04/17 (6 patients), 12/02/17 (11 patients), 12/01/17 (8 patients), 11/30/17 (9 patients), 11/29/17 (12 patients), 11/27/17 (7 patients), 11/25/17 (7 patients), 11/24/17 (3 patients), 11/21/17 (7 patients), 11/20/17 (13 patients), 11/17/17 (12 patients), 11/16/17 (8 patients), 11/15/17 (14 patients), 11/13/17 (7 patients), 11/11/17 (10 patients), 11/10/17 (13 patients), 11/09/17 (5 patients), 11/08/17 (9 patients), 11/06/17 (9 patients), 11/04/17 (10 patients), 11/03/17 (11 patients), 11/02/17 (10 patients), 11/01/17 (11 patients), 10/30/17 (2 patients), 10/28/17 (9 patients), 10/27/17 (7 patients), 10/26/17 (9 patients), 10/25/17 (4 patients), 10/23/17 (4 patients), 10/21/17 (6 patients), 10/20/17 (9 patients), 10/19/17 (7 patients), 10/18/17 (7 patients), 10/16/17 (6 patients), 10/14/17 (7 patients), 10/13/17 (8 patients), 10/11/17 (7 patients), 10/09/17 (6 patients), 10/07/17 (3 patients), 10/06/17 (4 patients), 10/05/17 (3 patients), 10/04/17 (6 patients), 10/02/17 (3 patients), 09/30/17 (18 patients), 09/29/17 (8 patients), 09/28/17 (10 patients), 09/27/17 (9 patients), 09/25/17 (5 patients), 09/23/17 (9 patients), 09/22/17 (10 patients), 09/21/17 (8 patients), 09/20/17 (8 patients), 09/18/17 (9 patients), 09/16/17 (14 patients), 09/15/17 (7 patients), 09/14/17 (10 patients), 09/09/17 (1 patient), 09/08/17 (7 patients), 09/07/17 (8 patients), 09/06/17 (9 patients), 09/02/17 (8 patients), 09/01/17 (10 patients), 08/26/17 (8 patients), 08/23/17 (15 patients), 08/21/17 (7 patients), 08/19/17 (14 patients), 08/18/17 (10 patients), 08/17/17 (13 patients), 08/16/17 (13 patients), 08/15/17 (1 patient), 08/14/17 (10 patients), 08/11/17 (12 patients), 08/10/17 (14 patients), 08/09/17 (8 patients), 08/05/17 (8 patients), 08/04/17 (2 patients), 08/03/17 (8 patients), 08/02/17 (8 patients), 07/31/17 (5 patients), 07/29/17 (11 patients), 07/28/17 (6 patients), 07/27/17 (11 patients), 07/26/17 (9 patients), 07/24/17 (11 patients), 07/22/17 (8 patients), 07/21/17 (12 patients), 07/20/17 (4 patients), 07/19/17 (8 patients), 07/18/17 (6 patients), 07/17/17 (9 patients), 07/14/17 (9 patients), 07/13/17 (12 patients), 07/12/17 (6 patients), 07/11/17 (13 patients), 07/10/17 (3 patients), 07/08/17 (13 patients), 07/07/17 (13 patients), 07/06/17 (18 patients), 07/05/17 (10 patients), 07/01/17 (13 patients), 06/30/17 (6 patients), 06/29/17 (4 patients), 06/28/17 (8 patients), 06/26/17 (14 patients), 06/24/17 (14 patients), 06/23/17 (7 patients), 06/22/17 (6 patients), 06/21/17 (12 patients), 06/19/17 (11 patients), 06/17/17 (5 patients), 06/16/17 (11 patients), 06/15/17 (9 patients), 06/14/17 (9 patients), 06/12/17 (9 patients), 06/10/17 (10 patients), 06/09/17 (12 patients), 06/08/17 (7 patients), 06/07/17 (7 patients), 06/05/17 (5 patients), 06/03/17 (7 patients), 06/02/17 (10 patients), 06/01/17 (9 patients), 05/31/17 (4 patients), 05/30/17 (8 patients), 05/27/17 (11 patients), 05/26/17 (16 patients), 05/25/17 (9 patients), 05/24/17 (6 patients), 05/23/17 (8 patients), 05/20/17 (13 patients), 05/19/17 (5 patients), 05/18/17 (6 patients), 05/17/17 (9 patients), 05/16/17 (8 patients), 05/15/17 (13 patients), 05/11/17 (11 patients), 05/10/17 (2 patients), 05/09/17 (8 patients), 05/08/17 (9 patients), 05/06/17 (12 patients), 05/05/17 (23 patients), 05/04/17 (10 patients), 05/02/17 (3 patients), 05/01/17 (9 patients), 04/29/17 (14 patients), 04/28/17 (13 patients), 04/27/17 (10 patients), 04/25/17 (5 patients), 04/24/17 (4 patients), 04/22/17 (6 patients), 04/21/17 (14 patients), 04/20/17 (6 patients), 04/18/17 (7 patients), 04/17/17 (12 patients), 04/14/17 (8 patients), 04/13/17 (5 patients), 04/12/17 (7 patients), 04/11/17 (5 patients), 04/08/17 (2 patients), 04/07/17 (8 patients), 04/06/17 (3 patients), 04/04/17 (9 patients), 04/03/17 (12 patients), 04/01/17 (8 patients), 03/31/17 (11 patients), 03/30/17 (5 patients), 03/28/17 (6 patients), 03/27/17 (8 patients), 03/25/17 (7 patients), 03/24/17 (7 patients), 03/23/17 (8 patients), 03/21/17 (6 patients), 03/20/17 (8 patients), 03/18/17 (6 patients), 03/17/17 (7 patients), 03/16/17 (6 patients), 03/15/17 (14 patients), 03/11/17 (8 patients), 03/10/17 (12 patients), 03/09/17 (11 patients), 03/07/17 (8 patients), 03/06/17 (10 patients), 03/04/17 (10 patients), 03/03/17 (6 patients), 03/02/17 (11 patients), 02/28/17 (5 patients), 02/27/17 (12 patients), 02/25/17 (10 patients), 02/24/17 (11 patients), 02/23

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**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and interview with Testing Person #A, the laboratory failed to follow their policy to conduct a quarterly quality assurance (QA) monitoring for 6 (1st and 4th quarter in 2016 and 1st, 2nd, 3rd, and 4th quarter in 2017) out of 8 (1st, 2nd, 3rd, 4th quarter in 2016 and 2017) quarters reviewed. Findings Included: Review of the "Quality Assurance Monitors" policy, states that quality assurance monitors will be completed and reviewed by the Laboratory Director on a quarterly basis. Review of the "Quality Assurance Monitors" found 1st and 4th quarter in 2016 not completed, and 1st, 2nd, 3rd, and 4th quarter in 2017 not done at all. During an interview on 02/02 /18 at 4:16 PM Testing Person #A confirmed that the quarterly quality assurance monitors were not being performed in 2017.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and interview with Testing Person #A and the Laboratory Director, the Laboratory Director failed to ensure API (American Proficiency Institute) proficiency testing samples were tested as required for 1 (3rd testing event in 2017) testing event out of 6 (1st, 2nd, 3rd testing events in 2016 and 2017) testing events reviewed (See D6016), failed to identify that the laboratory failed to document the quality control (QC) every day of testing for 427 days out of 539 days reviewed (See D6020), failed to identify the laboratory used expired reagent from 09/09/17 to 10 /25/17 (See D6025), failed to follow their policy to conduct a quarterly quality assurance (QA) monitoring for 6 (1st and 4th quarter in 2016 and 1st, 2nd, 3rd, and 4th quarter in 2017) out of 8 (1st, 2nd, 3rd, 4th quarter in 2016 and 2017) quarters reviewed (See D6021).

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on record review and interview with Testing Person #A and the Laboratory Director, the Laboratory Director failed to ensure API (American Proficiency Institute) proficiency testing samples were tested as required for 1 (3rd testing event in 2017) testing event out of 6 (1st, 2nd, 3rd testing events in 2016 and 2017) testing events reviewed. Findings Included: Review of "Daily Laboratory Log Sheet" revealed proficiency testing results recorded on 12/13/17 by two different Testing Personnel (Testing Person #B and Testing Person #E). During an interview on 02/02/18 at 4:04 PM Testing Person #A confirmed that the duplicate testing was done for competency evaluations for the testing personnel. Review of API instructions states that any verification testing be done "after the PT reporting deadline has passed." The deadline was 12/15/17 at 11:59 PM for the 3rd testing event in 2017. During an interview on 02/05/18 at 2:00 PM the Laboratory Director revealed that the proficiency testing was reviewed and that she signs off on testing personnel competency.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on record review and interview with Testing Person #A and the Laboratory Director, the Laboratory Director failed to identify that the laboratory failed to document the quality control (QC) every day of testing for 427 days out of 539 days reviewed. Findings Included: Review of "Daily Laboratory Log Sheet" revealed no documentation of a negative or positive control on 01/22/18 (10 patients), 01/20/18 (10 patients), 01/19/18 (12 patients), 01/18/18 (14 patients), 01/17/18 (14 patients), 01/15/18 (4 patients), 01/13/18 (12 patients), 01/12/18 (7 patients), 01/11/18 (8 patients), 01/10/18 (12 patients), 01/08/18 (8 patients), 01/06/18 (13 patients), 01/05/18 (14 patients), 01/04/18 (6 patients), 01/03/18 (11 patients), 12/30/17 (15 patients), 12/29/17 (12 patients), 12/28/17 (11 patients), 12/27/17 (14 patients), 12/26/17 (2 patients), 12/22/17 (8 patients), 12/21/17 (16 patients), 12/20/16 (6 patients), 12/18/17 (8 patients), 12/16/17 (7 patients), 12/15/17 (9 patients), 12/14/17 (12 patients), 12/13/17 (8 patients), 12/11/17 (6 patients), 12/09/17 (9 patients), 12/08/17 (9 patients), 12/07/17 (14 patients), 12/06/17 (10 patients), 12/04/17 (6 patients), 12/02/17 (11 patients), 12/01/17 (8 patients), 11/30/17 (9 patients), 11/29/17 (12 patients), 11/27/17 (7 patients), 11/25/17 (7 patients), 11/24/17 (3 patients), 11/21/17 (7 patients), 11/20/17 (13 patients), 11/17/17 (12 patients), 11/16/17 (8 patients), 11/15/17 (14 patients), 11/13/17 (7 patients), 11/11/17 (10 patients), 11/10/17 (13 patients), 11/09/17 (5 patients), 11/08/17 (9 patients), 11/06/17 (9 patients), 11/04/17 (10 patients), 11/03/17 (11 patients), 11/02/17 (10 patients), 11/01/17 (11 patients), 10/30/17 (2 patients), 10/28/17 (9 patients), 10/27/17 (7 patients), 10/26/17 (9 patients), 10/25/17 (4 patients), 10/23/17 (4 patients), 10/21/17 (6 patients), 10/20/17 (9 patients), 10/19/17 (7 patients), 10/18/17 (7 patients), 10/16/17 (6 patients), 10/14/17 (7 patients), 10/13/17 (8 patients), 10/11/17 (7 patients), 10/09/17 (6 patients), 10/07/17 (3 patients), 10/06/17 (4 patients), 10/05/17 (3 patients), 10/04/17 (6 patients), 10/02/17 (3 patients), 09

/30/17 (18 patients), 09/29/17 (8 patients), 09/28/17 (10 patients), 09/27/17 (9 patients), 09/25/17 (5 patients), 09/23/17 (9 patients), 09/22/17 (10 patients), 09/21/17 (8 patients), 09/20/17 (8 patients), 09/18/17 (9 patients), 09/16/17 (14 patients), 09/15/17 (7 patients), 09/14/17 (10 patients), 09/09/17 (1 patient), 09/08/16 (7 patients), 09/07/17 (8 patients), 09/06/17 (9 patients), 09/02/17 (8 patients), 09/01/17 (10 patients), 08/26/17 (8 patients), 08/23/17 (15 patients), 08/21/17 (7 patients), 08/19/17 (14 patients), 08/18/17 (10 patients), 08/17/17 (13 patients), 08/16/17 (13 patients), 08/15/17 (1 patient), 08/14/17 (10 patients), 08/11/17 (12 patients), 08/10/17 (14 patients), 08/09/17 (8 patients), 08/05/17 (8 patients), 08/04/17 (2 patients), 08/03/17 (8 patients), 08/02/17 (8 patients), 07/31/17 (5 patients), 07/29/17 (11 patients), 07/28/17 (6 patients), 07/27/17 (11 patients), 07/26/17 (9 patients), 07/24/17 (11 patients), 07/22/17 (8 patients), 07/21/17 (12 patients), 07/20/17 (4 patients), 07/19/17 (8 patients), 07/18/17 (6 patients), 07/17/17 (9 patients), 07/14/17 (9 patients), 07/13/17 (12 patients), 07/12/17 (6 patients), 07/11/17 (13 patients), 07/10/17 (3 patients), 07/08/17 (13 patients), 07/07/17 (13 patients), 07/06/17 (18 patients), 07/05/17 (10 patients), 07/01/17 (13 patients), 06/30/17 (6 patients), 06/29/17 (4 patients), 06/28/17 (8 patients), 06/26/17 (14 patients), 06/24/17 (14 patients), 06/23/17 (7 patients), 06/22/17 (6 patients), 06/21/17 (12 patients), 06/19/17 (11 patients), 06/17/17 (5 patients), 06/16/17 (11 patients), 06/15/17 (9 patients), 06/14/17 (9 patients), 06/12/17 (9 patients), 06/10/17 (10 patients), 06/09/17 (12 patients), 06/08/17 (7 patients), 06/07/17 (7 patients), 06/05/17 (5 patients), 06/03/17 (7 patients), 06/02/17 (10 patients), 06/01/17 (9 patients), 05/31/17 (4 patients), 05/30/17 (8 patients), 05/27/17 (11 patients), 05/26/17 (16 patients), 05/25/17 (9 patients), 05/24/17 (6 patients), 05/23/17 (8 patients), 05/20/17 (13 patients), 05/19/17 (5 patients), 05/18/17 (6 patients), 05/17/17 (9 patients), 05/16/17 (8 patients), 05/15/17 (13 patients), 05/11/17 (11 patients), 05/10/17 (2 patients), 05/09/17 (8 patients), 05/08/17 (9 patients), 05/06/17 (12 patients), 05/05/17 (23 patients), 05/04/17 (10 patients), 05/02/17 (3 patients), 05/01/17 (9 patients), 04/29/17 (14 patients), 04/28/17 (13 patients), 04/27/17 (10 patients), 04/25/17 (5 patients), 04/24/17 (4 patients), 04/22/17 (6 patients), 04/21/17 (14 patients), 04/20/17 (6 patients), 04/18/17 (7 patients), 04/17/17 (12 patients), 04/14/17 (8 patients), 04/13/17 (5 patients), 04/12/17 (7 patients), 04/11/17 (5 patients), 04/08/17 (2 patients), 04/07/17 (8 patients), 04/06/17 (3 patients), 04/04/17 (9 patients), 04/03/17 (12 patients), 04/01/17 (8 patients), 03/31/17 (11 patients), 03/30/17 (5 patients), 03/28/17 (6 patients), 03/27/17 (8 patients), 03/25/17 (7 patients), 03/24/17 (7 patients), 03/23/17 (8 patients), 03/21/17 (6 patients), 03/20/17 (8 patients), 03/18/17 (6 patients), 03/17/17 (7 patients), 03/16/17 (6 patients), 03/15/17 (14 patients), 03/11/17 (8 patients), 03/10/17 (12 patients), 03/09/17 (11 patients), 03/07/17 (8 patients), 03/06/17 (10 patients), 03/04/17 (10 patients), 03/03/17 (6 patients), 03/02/17 (11 patients), 02/28/17 (5 patients), 02/27/17 (12 patients), 02/25/17 (10 patients), 02/24/17 (11 patients), 02/23/17 (12 patients), 02/21/17 (6 patients), 02/20/17 (7 patients), 02/18/17 (13 patients), 02/17/17 (10 patients), 02/16/17 (10 patients), 02/13/17 (6 patients), 02/11/17 (15 patients), 02/10/17 (14 patients), 02/09/17 (11 patients), 02/07/17 (6 patients), 02/06/17 (8 patients), 02/04/17 (10 patients), 02/03/17 (12 patients), 02/02/17 (6 patients), 01/31/17 (6 patients), 01/28/17 (5 patients), 01/27/17 (8 patients), 01/26/17 (11 patients), 01/24/17 (6 patients), 01/23/17 (5 patients), 01/21/17 (6 patients), 01/20/17 (15 patients), 01/19/17 (7 patients), 01/18/17 (2 patients), 01/17/17 (11 patients), 01/16/17 (5 patients), 01/14/17 (11 patients), 01/13/17 (13 patients), 01/12/17 (7 patients), 01/10/17 (5 patients), 01/09/17 (5 patients), 01/08/17 (2 patients), 01/07/17 (13 patients), 01/06/17 (6 patients), 01/05/17 (18 patients), 12/24/16 (6 patients), 12/23/16 (6 patients), 12/22/16 (12 patients), 12/20/16 (3 patients), 12/19/16 (5 patients), 12/17/16 (8 patients), 12/16/16 (9 patients), 12/15/16 (8 patients), 12/13/16 (8 patients), 12/12/16 (3 patients), 12/09/16 (6 patients), 12/08/16 (8 patients), 12/06/16 (12 patients), 12/05/16 (2 patients), 12/03/16 (12 patients), 12/02/16 (5 patients), 12/01/17 (7

patients), 11/29/16 (10 patients), 11/28/16 (12 patients), 11/25/16 (1 patient), 11/22/16 (8 patients), 11/21/16 (8 patients), 11/19/16 (7 patients), 11/18/16 (6 patients), 11/17/16 (9 patients), 11/15/16 (4 patients), 11/14/16 (9 patients), 11/12/16 (8 patients), 11/11/16 (9 patients), 11/10/16 (9 patients), 11/08/16 (4 patients), 11/07/16 (5 patients), 11/05/16 (11 patients), 11/04/16 (5 patients), 11/03/16 (10 patients), 11/01/16 (12 patients), 10/29/16 (7 patients), 10/28/16 (8 patients), 10/27/16 (11 patients), 10/25/16 (3 patients), 10/24/16 (3 patients), 10/22/16 (7 patients), 10/21/16 (3 patients), 10/20/16 (8 patients), 10/18/16 (5 patients), 10/17/16 (4 patients), 10/15/16 (5 patients), 10/14/16 (2 patients), 10/13/16 (8 patients), 10/11/16 (7 patients), 10/10/16 (11 patients), 10/08/16 (4 patients), 10/07/16 (4 patients), 10/06/16 (6 patients), 10/04/16 (6 patients), 10/01/16 (4 patients), 09/30/16 (7 patients), 09/29/16 (9 patients), 09/27/16 (1 patient), 09/26/16 (9 patients), 09/24/16 (5 patients), 09/23/16 (5 patients), 09/22/16 (12 patients), 09/20/16 (3 patients), 09/19/16 (9 patients), 09/17/16 (11 patients), 09/16/16 (5 patients), 09/15/16 (6 patients), 09/13/16 (4 patients), 09/12/16 (7 patients), 09/10/16 (9 patients), 09/09/16 (10 patients), 09/08/16 (7 patients), 09/07/16 (1 patient), 09/06/16 (6 patients), 09/03/16 (4 patients), 09/02/16 (12 patients), 09/01/16 (8 patients), 08/31/16 (2 patients), 08/30/16 (4 patients), 08/29/16 (4 patients), 08/27/16 (9 patients), 08/26/16 (2 patients), 08/25/16 (7 patients), 08/23/16 (2 patients), 08/22/16 (4 patients), 08/20/16 (5 patients), 08/18/16 (17 patients), 08/16/16 (5 patients), 08/15/16 (4 patients), 08/13/16 (7 patients), 08/12/16 (9 patients), 08/11/16 (9 patients), 08/09/16 (2 patients), 08/08/16 (7 patients), 08/06/16 (6 patients), 08/05/16 (2 patients), 08/04/16 (8 patients), 08/02/16 (7 patients), 08/01/16 (12 patients), 07/30/16 (4 patients), 07/29/16 (9 patients), 07/28/16 (12 patients), 07/26/16 (3 patients), 07/25/16 (7 patients), 07/23/16 (13 patients), 07/22/16 (8 patients), 07/21/16 (11 patients), 07/19/16 (1 patient), 07/18/16 (3 patients), 07/16/16 (11 patients), 07/14/16 (11 patients), 07/12/16 (5 patients), 07/11/16 (4 patients), 07/09/16 (10 patients), 07/08/16 (4 patients), 07/07/16 (8 patients), 07/05/16 (10 patients), 07/02/16 (9 patients), 06/30/16 (11 patients), 06/28/16 (4 patients), 06/27/16 (10 patients), 06/25/16 (8 patients), 06/24/16 (5 patients), 06/23/16 (6 patients), 06/21/16 (5 patients), 06/20/16 (8 patients), 06/18/16 (5 patients), 06/17/16 (9 patients), 06/16/16 (7 patients), 06/14/16 (11 patients), 06/11/16 (3 patients), 06/10/16 (9 patients), 06/09/16 (4 patients), 06/07/16 (4 patients), 06/06/16 (5 patients), 06/04/16 (11 patients), 06/03/16 (7 patients), 06/02/16 (10 patients), 05/31/16 (4 patients), 05/27/16 (6 patients), 05/28/16 (6 patients), 05/26/16 (10 patients), 05/24/16 (9 patients), 05/23/16 (12 patients), 05/21/16 (9 patients), 05/20/16 (13 patients), 05/19/16 (9 patients), 05/17/16 (8 patients), 05/16/16 (6 patients), 05/14/16 (14 patients), 05/13/16 (14 patients), 05/12/16 (9 patients), and 05/10/16 (6 patients). During an interview on 02/02/18 at 3:30 PM Testing Person #A confirmed that the positive and negative QC was not documented. During an interview on 02/05/18 at 2:00 PM the Laboratory Director confirmed that logs were not reviewed daily.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on record review and interview with Testing Person #A and the Laboratory Director, the Laboratory Director failed to follow their policy to conduct a quarterly quality assurance (QA) monitoring for 6 (1st and 4th quarter in 2016 and 1st, 2nd, 3rd, and 4th quarter in 2017) out of 8 (1st, 2nd, 3rd, 4th quarter in 2016 and 2017) quarters reviewed. Findings Included: Review of the "Quality Assurance Monitors" policy, states that quality assurance monitors will be completed and reviewed by the Laboratory Director on a quarterly basis. Review of the "Quality Assurance Monitors" found 1st and 4th quarter in 2016 not completed, and 1st, 2nd, 3rd, and 4th quarter in 2017 not done at all. During an interview on 02/02/18 at 4:16 PM Testing Person #A confirmed that the quarterly quality assurance monitors were not being performed in 2017. During an interview on 02/05/18 at 2:00 PM the Laboratory Director confirmed that quality assurance reviews were done quarterly, however no documentation was provided.

**D6025**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(7)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that patient test results are reported only when the system is functioning properly.

This STANDARD is not met as evidenced by:  
Based on observation, record review, and interview with Testing Person #A and the Laboratory Director, the Laboratory Director failed to identify the laboratory used expired reagent from 09/09/17 to 10/25/17. Findings Included: During a tour of the testing area on 02/02/18 at 2:30 PM a bottle of Anti-D Gamma-clone (Lot#350013 Expired 09/08/17) was in the laboratory refrigerator. Review of the "Daily Laboratory Log Sheet" revealed that the expired reagent was used from 09/09/17 to 10/25/17. The expired reagent was used for a total of 32 day to include 217 patients. During an interview on 02/02/18 at 2:30 PM Testing Person #A confirmed that the reagent used was expired. During an interview on 02/05/018 at 2:00 PM the Laboratory Director revealed that the logs are reviewed quarterly.