

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2063353	(X3) Date Survey Completed 01/05/2018
Name of Provider or Supplier B Jeffrey Wallis Md Pa D/B/A	Street Address, City, State 6208 W Corporate Oaks Dr 2nd Fl, Crystal River, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Lab Manager, the laboratory failed to perform competency evaluations on 2 (Staff # D and E) out of 4 Personnel (#A, B, D, and E) for 2 of 2 years (2016-2017) reviewed. Findings Included: Review of Personnel Competency evaluations found no competencies for Staff #D for being the Testing person and for Staff #E for being a Clinical Consultant. During an interview on 01/05/18 at 11:12 AM the Lab Manager confirmed that competency evaluations where not performed on Staff #D and #E.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Lab Manager, the laboratory failed to verify the accuracy of testing by performing peer reviews twice a year for 2 out of 2 years (2016-2017) reviewed. Findings Included: Review of peer reviews revealed that they were performed 11/17 and 12/16. During an interview on 01/05/18 at 11:27 AM the Lab Manager confirmed that the peer reviews were only conducted once a year.</p>

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 the Lab Manager, the laboratory failed to document the humidity for 3 (09/16, 02/17, and 11/17) out of 4 (03/16, 09/16, 02/17, and 11/17) months reviewed. Findings Included: Review of humidity logs for the laboratory found that no humidity had been documented in 09/16, 02/17, and 11/17. During an interview on 01/05/18 at 11:45 AM the Lab Manager confirmed that after 03/16 the humidity was not being documented on the log.

D5800

POSTANALYTIC SYSTEMS

CFR(s): 493.1290

Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on record review and interview with the Lab Manager, the laboratory failed to include the location of where the testing was performed on 4 out of 4 patient reports (#1-4) reviewed. See D5805 which is a repeat deficiency from the 11/12/15 recertification survey.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Lab Manager, the laboratory failed to include the location of where the testing was performed on 4 out of 4 patient reports

(#1-4) reviewed. This is a repeat deficiency from the 11/12/15 recertification survey. Findings Included: Review of patient final reports pulled from 04/06/16 (#1), 09/21/16 (#2), 02/21/17 (#3), and 10/31/17 (#4) revealed that all of the reports did not have the address of the location of where the testing was performed. During an interview on 01/05/18 at 12:30 PM the Lab Manager confirmed that the address of the location of where the testing was performed was not on the final reports. Review of the Plan of Correction (signed 12/22/15 by the Lab Manager) revealed that this is a repeat deficiency from the 11/12/15 recertification survey. The Plan of Correction stated that "They action plan is all old report forms are being disposed of. The printer has been informed of new address. When lab restarts histo supervisor will monitor new forms for correct address and document daily on log." This correction was to be completed by 12/30/15.