

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1071498	(X3) Date Survey Completed 01/08/2019
Name of Provider or Supplier Foster J Boyd Regional Cancer Center	Street Address, City, State 31 Farquhar Avenue, Wilmington, OH	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews with the Technical Supervisor (TS), the laboratory failed to document the handling, preparation, processing, examination and each step in the testing and reporting of proficiency testing (PT) results. Findings Include: 1. Review of the laboratory's policies and procedures titled "CMH Regional Health System Policy and Procedure", policy number "Lab-GC.010" provided on the date of the inspection, found the following statement: Review and Reporting of Lab Results of PT Samples "2. The Senior Tech, Laboratory Manager or Laboratory Operations Supervisor will sign the results then fax, mail or enter results online to CAP." 2. Review of the attestation form from CAP kit 30363663 2 08 63 revealed a signature from Test Personnel #2 on the Director or designee attestation line. 3. The TS confirmed Test Personnel #2 was not a Senior Tech, Laboratory Manager or Laboratory Operations Supervisor and did not have the designated authority to sign the CAP attestation page. The interviews occurred on 01/08/2019 at 11:45 AM.</p>
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Technical Supervisor (TS), the laboratory failed to establish and follow written policies and procedures to assess the competency of the General Supervisor (GS), and Testing Personnel (TP) based on the responsibilities of their positions. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 12/13 /2018, revealed three individuals listed as TP, and one individual listed as GS. 2. Review of the laboratory's policy and procedure manual titled "CMH Regional Health System Policy and Procedure", provided on the date of the inspection, approved via electronic signature and date by the Laboratory Director, did not find any mention of a competency assessment policy and procedures for TP and the GS. 3. The Surveyor requested the laboratory's competency assessment policies and procedures from the TS. The TS confirmed the laboratory did not establish and follow a competency assessment policy and procedure for the assessment of the TP and the GS, however did assess the competency of all TP and the GS for the high complexity chemistry and hematology testing based on the responsibilities of each position. The TS was unable to provide the requested policy and procedure documentation on the date of the inspection. The interview occurred on 1/08/2019 at 12:01 PM.

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 an interview with the Technical Supervisor (TS), the laboratory failed to ensure the test report indicated the correct name and address of the laboratory location where testing was performed. Findings Include: 1. Review of two out of two of the laboratory's test reports, on the date of the inspection, revealed the following address on both test reports reviewed: "Clinton Memorial Hospital 610 West Main Street Wilmington, OH 45177" 2. The TS confirmed all testing from the above reviewed reports was completed at: Foster J Boyd Regional Cancer Center 31 Farquhar Avenue Wilmington, OH 45177 3. The TS also confirmed the name and address where testing was completed was incorrectly indicated on all final test reports from before 2016, (specific dates not known), to the date of the inspection. The interview occurred 01/08/2019 at 11:56 AM.