

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0185151	(X3) Date Survey Completed 01/31/2018
Name of Provider or Supplier Ph Dubois, Clearfield Campus	Street Address, City, State 809 Turnpike Avenue, Clearfield, PA	
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
D5305	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.</p> <p>This STANDARD is not met as evidenced by: Based on review of specimen test requisitions and interviews it was determined that the laboratory failed to ensure that four of four nongynecologic test requisitions from November through December 2017 solicited the sex of the patient. Findings include: 1. The Survey Team reviewed specimen test requisitions used for submitting nongynecologic outpatient specimens. The test requisitions failed to solicit the sex of the patient. Requisitions include: 03-NG-17-0000545 03-NG-17-0000548 03-NG-17-0000560 03-NG-17-0000579 2. During an interview on 1/29/18 at 11:45 AM, STAFF A stated that the requisitions were used by outpatient offices and confirmed that the test requisitions did not solicit the sex of the patient. 3. During an interview on 1/30/18 at 3:00 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.</p>

<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of thirty-four laboratory policies and procedures, observation and interviews it was determined that the laboratory failed to follow one written policy and procedure. Cross refer to D5821 Findings include: 1. The laboratory failed to follow the written procedure titled FINAL, ADDENDUM, AND CORRECTED CYTOLOGY REPORT FORMAT POLICY (signed and dated by the Laboratory Director on 12/20/17) which stated: "A copy of the original final report and corrected or addendum report are retained in the legal health record. The new report is automatically sent to the ordering physician by Cerner."</p>
<p>D5631</p>	<p>CYTOLOGY CFR(s): 493.1274(c)(6)</p> <p>(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (6) An evaluation of the case reviews of each individual examining slides against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, corrective actions taken.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures for a program to evaluate the case reviews of three of three Technical Supervisors against the laboratory's overall statistical values in 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for a program to evaluate the case reviews of three of three Technical Supervisors against the laboratory's overall statistical values. 2. The Survey Team requested and the laboratory failed to provide records for comparative reviews to evaluate the case reviews of three of three Technical Supervisors against the laboratory's overall statistical values. Technical Supervisors include: Technical Supervisor A Technical Supervisor B Technical Supervisor C 3. During an interview on 1/29/18 at 2:15 PM, STAFF A stated that laboratory did not compare the individual case reviews against the laboratory's overall statistics. 4. During an interview on 1/30/18 at 3:00 PM, the Laboratory Director /Technical Supervisor A confirmed these findings.</p>
<p>D5821</p>	<p>TEST REPORT CFR(s): 493.1291(k)</p> <p>When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue</p>

corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

Based on review of final cytology test reports and interviews it was determined that the laboratory failed to maintain duplicates of five of five original final test reports from 2017, when a correction was made to the original final test report. Findings include: 1. The Survey Team requested and the laboratory failed to provide a duplicate of the original final test report for five of five reports that were corrected. Reports include: 03-NG-17-0000115 03-NG-17-0000390 03-NG-17-0000456 03-NG-17-0000576 03-NG-17-0000577 2. During an interview on 1/30/18 at 8:15 AM, STAFF A stated that the original test report could not be printed from the laboratory information system (LIS) when a correction was made. 3. During an interview on 1/30/18 at 10:40 AM, STAFF A stated that a new LIS was implemented in March 2017 and the new LIS did not maintain copies of the original test reports. 4. During an interview on 1/30/18 at 3:00 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.

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