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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>39D0189583                  | <b>(X3) Date Survey Completed</b><br>05/27/2021 |
| <b>Name of Provider or Supplier</b><br>Pottsville Cancer Clinic  | <b>Street Address, City, State</b><br>700 Schuylkill Manor Road Suite 7, Pottsville, PA |   |
| 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>  |
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| <b>D5209</b>              | <p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b><br/>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:<br/>Based on review of the laboratory's procedure manuals , review of testing personnel records and interview with testing personnel (TP) #1, the laboratory failed to establish a complete competency assessment procedure to assess new TP (1 of 4) for competency in 2019. Findings include: 1. On the day of survey, 05/27/2021, TP#1 could not provide a complete competency assessment procedure to assess testing personnel for competency at least semiannually during the first year the individual tests patient specimens. 2. TP#4 was assessed for competency on December 2019 and again in December 2020. 3. TP#1 confirmed TP#4 was not assessed semiannually in 2019 on 05/27/2021 around 9:30 am.</p> |
| <b>D5407</b>              | <p><b>PROCEDURE MANUAL</b><br/>CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the Clinical Diagnostics Solutions (CDS) M series M32 complete blood count (CBC) analyzer procedure, validation records and interview with testing personnel (TP) #1, the laboratory director (LD) failed to approve, sign, and date the new CBC analyzer procedure and validation study before testing began in 2019.</p>  |

Findings include: 1. On the day of survey, 05/27/2021, review of the CDS M series M32 CBC analyzer procedure and validation study revealed, the current laboratory director did not sign the forms before testing began on May 2019. 2. On the day of survey, 05/27/2021, the LD signed the procedure and instrument validation around 11:45 am.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:  
Based on observation of the laboratory and interview with the testing personnel (TP) #1, the laboratory failed to establish a maintenance policy to assess the maintenance /function for 2 of 2 thermometers used to monitor the temperatures of reagents used on Clinical Diagnostics Solutions (CDS) M series M32 complete blood count (CBC) analyzer from 2019 to the day of survey. Findings Include: 1. On the day of survey, 05/27/2021, the surveyor observed 1 of 1 unlabeled mercury refrigerator thermometer and 1 of 1 Ortho Biotech clock/thermometer used to monitor the temperature of reagents stored at room temperature for the CDS M series M32 CBC analyzer. 2. The laboratory could not provide documentation of maintenance/function checks performed on 2 of 2 thermometers. 3. The laboratory could not provide a maintenance policy for the thermometers. 4. TP #1 confirmed the findings above on 05/27/2021 around 11:45 am.

**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 the testing personnel (TP) #1, the laboratory director (LD) failed to assure that quality assessment programs were maintained from May 2019 to April 2021. Findings include: 1. On the day of survey, 05/27/2021, review of the daily log sheet revealed, 24 of 24 daily log sheets were not reviewed or signed by the LD from May 2019 to April 2021. 2. In 2019 - 3 of 8 months of daily log sheets were not reviewed. 3. In 2021 - 4 of 4 months of daily log sheets were not reviewed. 4. From May 2019 to April 2021, the following daily log

sheets were reviewed by TP#1, which is not listed as a technical consultant. - 2019: 5 of 8 months. - 2020: 12 of 12 months. 5. TP #1 and the LD confirmed the findings above on 05/27/2021 around 11:50 pm.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of testing personnel records and interview with testing personnel (TP) #1 the laboratory director failed to ensure that prior to testing patients specimens, 1 of 4 TP received the appropriate training for performing complete blood count (CBC) tests in 2019. Findings include: 1. On the day of survey, 05/27/2021, TP#1 could not provide the training records for TP#4 performing CBC tests from December 2019 to May 27, 2021. 2. TP#1 confirmed the finding above on 05/27/2021 around 9: 30 am.