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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D0011492 | (X3) Date Survey Completed 10/19/2022 |
| Name of Provider or Supplier Corry Memorial Hospital | Street Address, City, State 965 Shamrock Lane, Corry, 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 |
|---------------------------|--|
| 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 review of the laboratory's competency assessment records and interview with technical supervisor #1(TS), the laboratory failed to establish a competency assessment procedure to assess the competency of 1 of 2 technical supervisors, and 6 of 7 general supervisors (GS) for their supervisory roles from 08/12/2020 to the date of survey. Findings include: 1. On the day of survey, 10/19/2022 at 09:01 am, the laboratory could not provide a competency assessment policy to assess the competency of the following personnel for their supervisory skills from 08/12/2020 to 10/19/2022: - 1 of 2 TS (CMS 209, personnel #2) - 6 of 7 GS (CMS 209, personnel #3, #4, #5, #6, #7, #8) 2. The laboratory could not provide documentation for delegation of duties for TS #1 (CMS 209, personnel #2). 3. The laboratory could not provide competency assessment documents for 6 of 7 GS (CMS 209, personnel #3, #4, #5, #6, #7, #8). 4. TS #1 confirmed the findings above on 10/19/2022 around 04:30 pm. *This is a repeat deficiency.</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:</p> |

Based on lack of documentation and interview with technical supervisor #2 (TS), the laboratory failed to verify twice annually the accuracy of acetone examinations performed from 08/12/2020 through the date of survey. Findings include: 1. On the day of survey, 10/19/2022 at 11:31 am., the laboratory could not provide documentation of verification of accuracy for acetone examinations performed from 08/12/2020 to 10/19/2022. 2. TS #2 confirmed the findings above on 10/19/2022 around 04:30 pm.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with technical consultant #2 (TC), the laboratory failed to perform calibration verification at least once every six months for the Siemens Dimension Chemistry Analyzer from 08/12/2020 to the date of survey. Findings include: 1. On the date of survey, 10/19/2022 at 02:17 pm, the laboratory could not provide calibration verification records for the required analytes tested on the Siemens Dimension chemistry analyzer from 08/12/2020 to 10/19/2022. 2. TC #2 confirmed the findings above on 10/19/2022 around 04:30 pm.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:
Based on the review of American Proficiency Institute (API) proficiency testing (PT) records and interview with technical supervisor #2 (TS), the laboratory director (LD) failed to review and evaluate the laboratory's performance that required a corrective

action for 1 of 3 API Chemistry Core events in 2021. Findings Include: 1. On the day of survey, 10/19/2022 at 11:27 am, review of API PT records revealed the following analytes from the API 2021-Chemistry Core-3rd Event were not assessed by the laboratory: -Routine Chemistry: TIBC, measured - 60% -Hematology: Hemoglobin (blood oximetry) - 20% -Hematology: Methemoglobin - 20% -Hematology: Oxyhemoglobin - 40% 2. The laboratory could not provide documentation of corrective action for the API 2021 Chemistry Core-3rd Event. 3. TS#2 confirmed the findings above on 10/12/2021 around 04:30 pm.

D6125

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) competency assessment records, and interview with technical supervisor #2 (TS), the TS failed to assess the competency for 7 of 7 TP through external proficiency testing samples or internal blind testing samples for tests performed in the Chemistry, Hematology, Microbiology, Immunohematology, and Urinalysis departments in 2021. Findings include: 1. On the day of survey, 10/19/2022 at 10:13 am, review of TP competency assessment records revealed annual competencies performed in 2021 did not include the assessment of external proficiency testing samples or internal blind testing samples for 7 of 7 TP (CMS 209 personnel # 3, #4, #5, #6, #7, #8, and #9) who performed testing in Chemistry, Hematology, Microbiology, Immunohematology, and Urinalysis departments. 2. TS #2 confirmed the finding above on 10/12/2022 around 04:30 pm.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's competency assessment testing personnel records and interview with technical supervisor #1 (TS), the TS failed to evaluate and document the performance of 1 of 7 testing personnel (TP) responsible for testing performed in the Chemistry, Hematology, Microbiology, Immunohematology, and Urinalysis departments at least semi-annually during their first year from August 2021 to the day of survey. Findings include: 1. On the date of survey, 10/19/2022 at 09:40 am, the laboratory could not provide semi-annual competency assessment documentation for 1 of 7 TP (CMS 209 personnel #7) who performed testing in the Chemistry, Hematology, Microbiology, Immunohematology, and Urinalysis departments during their first year. 2. TS #1 confirmed that TP #7 started patient testing in August 2021. 3. The laboratory performed 370,814 non-waived examinations in 2021 (CMS 116 annual volume) 4. TS #1 confirmed the findings above on 10/19/2022 around 04:30 pm.