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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D0011492 | (X3) Date Survey Completed 08/13/2020 |
| 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:</p> <p>A. Based on review of competency assessment records and interview with the technical supervisor (TS) #1 and #2, the laboratory failed to assess the competency for 1 of 9 testing personnel (TP) for their 1st year of semiannual competency in 2019 and 2020. Findings Include: 1. The Orientation and competency policy states, "Competency assessment must be performed at the following frequency: At least semi annually during the first year an employee tests patient specimen and at least annually thereafter". 2. On the day of survey, 08/12/2020, review of TP competency assessment recorded reviewed, the laboratory did not document the competency assessment for 1 of 9 TP (TP #6) hired 01/23/2019 for their semi annual competency in 2019 and 2020 for testing performed in the laboratory departments of microbiology, clinical chemistry, hematology. immunochemistry, serology, toxicology, and urinalysis. 3. The TS #1 and #2 confirmed the above findings on 08/12/2020 around 10:25 am. B. Based on review of the laboratory policies and interview with the technical supervisor #1 and #2, the laboratory failed to establish a competency assessment policy to assess the competency for 2 of 3 laboratory personnel for their regulatory responsibilities in 2018, 2019 and 2020. Findings Include: 1. On the day of survey, 08/12/2020, the laboratory could not provide a competency assessment policy or documentation of competency assessment performed for 2 of 3 laboratory personnel (On the CMS 2019 Testing Personnel form, listed as a technical consultants, technical supervisors and general supervisors) in 2018, 2019 and 2020. 2. The TS #1 and #2 confirmed the above finding on 08/12/2020 around 10:30 am.</p> |

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory quality control (QC) records and interview with the technical supervisor (TS) #1 and #2, the laboratory failed to perform quality control each day of patient testing for the one step oxycodone test cards from 05/10/2018 to 08/13/2020. Findings Include: 1. On the day of survey, 08/12/2020, review of the one step oxycodone test card kit QC records revealed, the laboratory did not perform QC each day of patient testing from 05/10/2018 to 08/13/2020. 2. In 2018 (05/10/2018 to 12/31/2018), 133 oxycodone test cards were analyzed. 3. In 2019 (01/01/2019 to 12/31/2019), 206 oxycodone test cards were analyzed. 4. In 2020 (01/01/2020 to 08/13/2020), 118 oxycodone test cards were analyzed. 5. The TS #1 and #2 confirmed the above finding on 08/13/2020 around 10:15 am.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the procedure manual and interview with the technical supervisor (TS) #1 and #2, the LD failed to ensure a quality assessment (QA) policy was established to assess the quality of laboratory services provided from 2018, 2019 and 2020. Findings Include: 1. On the date of survey, 08/12/2020, the TS could not provide a QA policy that assessed the laboratory's pre-analytical, analytical, and post-analytical processes from 05/10/2018 to 08/13/2020. 2. The TS #1 and #2 confirmed on 08/13/2020 around 08:45 am.