

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2138930	(X3) Date Survey Completed 05/11/2023
Name of Provider or Supplier Redmed Of Crosstown	Street Address, City, State 11611 Hwy 51 S, Atoka, TN	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policies, proficiency testing (PT) records, and staff interview the laboratory failed to follow their policies for unacceptable results on the Medical Laboratory Evaluation (MLE) PT 2022 event one (one of one event with unacceptable results for 2021, 2022, and 2023). The findings include: 1. Review of the laboratory policies related to PT titled "Proficiency Testing" and "PROTOCOL FOR SUCCESSFUL PERFORMANCE OF PROFICIENCY TESTING" revealed that any score less than 100% the samples should be reran and results evaluated by the technical consultant (TC). 2. Review of the laboratory's MLE PT records revealed 2022 Event one sample HD-3 had unacceptable results for the white blood count (WBC), red blood count (RBC), hemoglobin (Hgb), hematocrit (Hct), and platelet count (PLT) analytes. Documentation of unacceptable result review was not available. 3. Interview on 05/11/2023 at 1:00 p.m. with the technical consultant confirmed the laboratory did not follow their own policy for unacceptable results for the MLE PT event one in 2022.</p>
D6045	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7)</p> <p>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services</p>

performed;

This STANDARD is not met as evidenced by:

Based on review of laboratory records, personnel training records, and staff interview, the technical consultant failed to review training documents for four of seven testing personnel (TP) for the new Sysmex XP300 complete blood count (CBC) instrument for patient testing in July 2022. The findings include: 1. Review of laboratory records for the Sysmex XP300 (serial C4846) CBC instrument revealed the laboratory began using the instrument July 2022. 2. Review of the laboratory personnel training records for the Sysmex XP300 CBC instrument revealed the following training documents lacking the signature of the technical consultant: TP one training dated 07/15/2022. TP two training dated 07/14/2022. TP three training dated 07/14/2022. TP four training dated 07/15/2022. 3. Interview on 05/11/2023 at 1:00 p.m. with the technical consultant confirmed the former technical consultant failed to review the training for TP one, two, three, and four for the new Sysmex XP300 CBC instrument for patient testing in July 2022.

D6055

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, personnel records, and staff interview, the technical consultant failed to evaluate the competency for four of seven testing personnel (TP) for the use of the new Sysmex XP300 complete blood count (CBC) instrument prior to patient testing in 2022. The findings include: 1. Review of laboratory records for the Sysmex XP300 (serial C4846) CBC instrument revealed the laboratory began using the instrument for patient testing in July 2022. 2. Review of laboratory personnel records revealed no documentation of competency assessment evaluation for TP 1, TP 2, TP 3, and TP 6 (four of seven TP) prior to CBC patient testing with the Sysmex XP300 in 2022. 3. Interview on 05/11/2023 at 1:00 p.m. with the technical consultant confirmed the former technical consultant failed to assess competency for TP one, two, three, and six for the new Sysmex XP300 CBC instrument prior to patient testing in July 2022.