

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2132802	(X3) Date Survey Completed 09/10/2021
Name of Provider or Supplier Children's Clinic Of Rusk, Pllc	Street Address, City, State 1375 Dickinson Drive, Rusk, TX	
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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's American Proficiency Institute (API) proficiency testing records for 2019, 2020 and 2021, and staff interview, it was revealed that the laboratory failed to test proficiency testing samples the same number of times that it would test its patient samples for six of six proficiency testing events reviewed from 2019, 2020, and 2021. Findings include: 1. A review of the laboratory's policy titled 'Horiba Micros 60 Procedure Manual' revealed the following: "Running Patient Samples: - if a flag appears go to Main Menu then to Service and Back Flush- run the sample again" 2. A review of the laboratory's API proficiency testing records from 2019, 2020, and 2021 revealed the following proficiency testing samples had flags on the reports and there was no documentation of the sample being re-run: a) 2019 Hematology/Coagulation second event: HEM-06 Flag: G3 HEM-07 Flag: G1 and G3 HEM-08 Flag: G1 and G3 HEM-09 Flag: G3 HEM-10 Flag: G3 b) 2019 Hematology/Coagulation third event: HEM-11 Flag: G3 HEM-12 Flag: G3 HEM-13 Flag: G3 HEM-14 Flag: G3 HEM-15 Flag: L1 and G3 c) 2020 Hematology/Coagulation first event: HEM-01 Flag: G3 HEM-02 Flag: G1 and G3 HEM-03 Flag: G1 and G3 HEM-04 Flag: G3 HEM-05 Flag: G3 d)</p>

2020 Hematology/Coagulation second event: HEM-06 Flag: G1 and G3 HEM-07 Flag: L1 and G3 HEM-08 Flag: G3 HEM-09 Flag: G3 HEM-10 Flag: G3 e) 2020 Hematology/Coagulation third event HEM-11 Flag: G1 and G3 HEM-12 Flag: L1, G1 and G3 HEM-13 Flag: G3 HEM-14 Flag: G1 and G3 HEM-15 Flag: G1 and G3 f) 2021 Hematology/Coagulation second event HEM-06 Flag: G3 HEM-07 Flag: G1 and G3 HEM-08 Flag: G1 and G3 HEM-09 Flag: G3 HEM-10 Flag: G1 and G3 3. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 9/6/21) on 9/10/21 at 9:35 a.m. in the break room, after review of the records, confirmed the above findings.

D2121

HEMATOLOGY

CFR(s): 493.851(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's American Proficiency Institute (API) proficiency test results and staff interview, it was revealed that the laboratory failed to attain a score of at least 80 percent for the analyte White Blood Cell Differential for one of three testing events in 2020. Findings include: 1. A review of the laboratory's API proficiency test results for the 2020 Hematology/Coagulation third event revealed the laboratory received an unacceptable score of 47% for the analyte White Blood Cell Differential. 2. Further review of the laboratory's API proficiency test results for the 2020 Hematology/Coagulation third event revealed the laboratory received a grade of unacceptable for three out of five samples, resulting in a 40 percent for the analyte Monocytes. The following three unacceptable results were submitted: Sample: HEM-11 Reported result: 13.5 Expected result: 4.5 - 10.0 Sample: HEM-13 Reported result: 24.1 Expected result: 3.9 - 18.8 Sample: HEM-15 Reported result: 13.9 Expected result: 4.9 - 9.6 3. Further review of the laboratory's API proficiency test results for the 2020 Hematology/Coagulation third event revealed the laboratory received a grade of unacceptable for five out of five samples, resulting in a 0 percent for the analyte Lymphocytes. The following five unacceptable results were submitted: Sample: HEM-11 Reported result: 21.0 Expected result: 22.4 - 30.7 Sample: HEM-12 Reported result: 11.2 Expected result: 11.6 - 15.7 Sample: HEM-13 Reported result: 38.0 Expected result: 43.8 - 60.3 Sample: HEM-14 Reported result: 11.7 Expected result: 12.1 - 16.0 Sample: HEM-15 Reported result: 22.0 Expected result: 24.4 - 32.2 * The 40 percent for Monocytes and the 0% for Lymphocytes constituted the overall score of 47 percent for the analyte White Blood Cell Differential. 4. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 9/6/21) on 9/10/21 at 9:35 a.m. in the break room, after review of the records, confirmed the above findings.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:

I. Based on a review of the laboratory's policies, quality control (QC) records for the Horiba Micros 60 hematology analyzer, and staff interview, it was revealed that the laboratory failed to follow its own written procedure for performing corrective action for unacceptable quality control for three of 22 QC runs in October 2020. Findings include: 1. A review of the laboratory's policy titled 'Horiba Micros 60 Procedure Manual' revealed the following: "Quality Control Procedures: If the QC results are outside the acceptable limits or flags have been triggered reject the results. If results are rejected, gently mix that control and run again." 2. A review of QC records for the Horiba Micros 60 hematology analyzer for October 2020 revealed the laboratory failed to follow their own written procedure for troubleshooting unacceptable QC on the following three dates: - 10/26/20 High Control Lot: MX 426 Gra # = 14.40 Acceptable range: 14.60 - 17.40 * No documentation of the QC being re-run - 10/29/20 High Control Lot: MX426 Gra # = 14.40 Acceptable range: 14.60 - 17.40 * No documentation of the QC being re-run - 10/30/20 High Control Lot: MX426 Gra # = 14.50 Acceptable range: 14.60 - 17.40 * No documentation of the QC being re-run 3. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 9/6/21) on 9/10/21 at 10:20 a.m. in the break room, after review of the records, confirmed the above findings. Key: Gra # = Absolute Granulocytes II. Based on a review of the laboratory's policies, a random review of patient's complete blood count (CBC) test records, and staff interview, it was revealed that the laboratory failed to follow its procedure six of six times from December 2020 to September 2021, by not performing a slide review when patient's CBC results were flagged by the Horiba Micros 60 hematology analyzer. Finding include: 1. A review of the laboratory's policy titled "Horiba Micros 60 Procedure Manual' revealed the following: "Criteria for Reflex to Slide Review and Flags Flags: L1, M2, G1, G2, G3 WBC flag- indicates abnormal number of cells - Slide Review" 2. A random review of patient's CBC test records from December 2020 to September 2021 revealed the following 6 patient samples were run on the Horiba Micros 60 hematology analyzer, the results were flagged by the analyzer, and there was no documentation that a slide review was performed as per the laboratory's policy: Date: 12/2/20 Patient: 65279 Flags present on CBC report: M2 Date: 12/21/20 Patient: 65279 Flags present on CBC report: G1 and G2 Date: 8/19/21 Patient: 60290 Flags present on CBC report: G1 and G2 Date: 8/20/21 Patient: 60290 Flags present on CBC report: G1 and G2 Date: 8/26/21 Patient: 65279 Flags present on CBC report: M2, G1, G2 Date: 9/10/21 Patient: 090909 Flags present on CBC report: G1 and G2 3. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 9/6/21) on 9/10/21 at 10:50 a.m. in the break room, after review of the records, confirmed the above findings. Key: WBC = White Blood Cell