

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0948461	(X3) Date Survey Completed 10/11/2018
Name of Provider or Supplier Brownsville Kiddie Health Center	Street Address, City, State 95 East Price Road Building F Suite A, Brownsville, 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	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was 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. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of patient test records from September 2018, and staff interview, it was revealed the laboratory failed to have documentation of following its policy to invalidate differential results with flags. The findings were: 1. A review of the laboratory's policy titled "Policy for Handling Flagged CBC Differentials" (approved by the laboratory director on 09/01/2016) revealed: "It will be the policy of this laboratory to rerun flagged CBC results. If the second run still shows flags, then the lab will evaluate flagged differentials according</p>

to the procedure in the unit's operators manual. See that the sample requirements are met, that the unit is in good working order, and that the testing procedure is correctly followed. If the flags disappear, then report that result. If the flags persist, then it will be considered an abnormal differential and will be invalidated and/or should be sent out for analysis." 2. A sampling of patient test records from September 2018 identified the following patient results with flags which were reported to the provider: Date ID Flag 09/07 12-26-2017 OM 09/07 7-12-18 OM 09/07 9-15-17 BD 09/07 02-03-2017 OM 09/10 09/02/2017 OM 09/12 3/3/2016 BD 09/12 08/30/2017 OM 09/26 09-02-2017 BD 3. The laboratory was asked to provide documentation of invalidating the differential results with flags or of sending the samples out for additional testing as required by its policy. No documentation was provided. 4. An interview with the technical consultant on 10/11/2018 at 1110 hours in the office - after his review of the records- confirmed the findings.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's verification studies performed on the Medonic M-series hematology analyzer, review of patient normal ranges currently in use, and staff interview, it was revealed the laboratory failed to have documentation of verifying patient normal ranges. The findings were: 1. A review of the laboratory's verification studies performed on the Medonic M-series hematology analyzer (serial number 29442) in October 2017 revealed the laboratory failed to have documentation of verifying patient normal ranges. 2. A review of patient normal ranges currently in use by the laboratory revealed the following 4 patient normal ranges: a) 0 - 2 years WBC 6.0 - 14.0 LYM 1.0 - 5.0 MID 0.1 - 1.0 GRAN 2.0 - 8.0 LYM% 25.0 - 50.0 MID% 2.0 - 10.0 GRA% 50.0 - 80.0 RBC 3.80 - 5.40 HGB 10.5 - 14.0 HCT 35.0 - 42.0 MCV 72.0 - 88.0 MCH 24.0 - 30.0 MCHC 32.0 - 36.0 RDW% 11.5 - 16.0 PLT 150 - 500 MPV 8.0 - 11.0 b) 2 - 17 years WBC 4.0 - 10.5 LYM 1.0 - 5.0 MID 0.1 - 1.0 GRAN 2.0 - 8.0 LYM% 25.0 - 50.0 MID% 4.0 - 13.0 GRA% 50.0 - 80.0 RBC 4.20 - 5.60 HGB 12.5 - 16.1 HCT 36.0 - 47.0 MCV 78.0 - 95.0 MCH 26.0 - 32.0 MCHC 32.0 - 36.0 RDW% 11.5 - 14.0 PLT 150 - 500 MPV 8.0 - 11.0 c) Adult female WBC 4.0 - 10.5 LYM 1.0 - 5.0 MID 0.1 - 1.0 GRAN 2.0 - 8.0 LYM% 25.0 - 50.0 MID% 2.0 - 10.0 GRA% 50.0 - 80.0 RBC 4.10 - 5.30 HGB 12.0 - 15.0 HCT 35.0 - 45.0 MCV 78.0 - 95.0 MCH 26.0 - 32.0 MCHC 32.0 - 36.0 RDW% 11.5 - 14.0 PLT 150 - 500 MPV 8.0 - 11.0 d) Adult male WBC 4.0 - 10.5 LYM 1.0 - 5.0 MID 0.1 - 1.0 GRAN 2.0 - 8.0 LYM% 25.0 - 50.0 MID% 2.0 - 10.0 GRA% 50.0 - 80.0 RBC 4.20 - 5.60 HGB 12.5 - 16.1 HCT 36.0 - 47.0 MCV 78.0 - 95.0 MCH 26.0 - 32.0 MCHC 32.0 - 36.0 RDW% 11.5 - 14.0 PLT 150 - 500 MPV 8.0 - 11.0 WBC 5.0 - 14.5 LYM 1.8 - 9.4 MID 0.2 - 1.9 GRAN 1.5 - 7.1 LYM% 63.0 - 65.0 MID% 4.0 - 13.0 GRA% 30.0 - 49.0 RBC 3.7 - 5.00 HGB 11.2 - 14.5 HCT 32.0 - 44.0 MCV 75.0 - 96.0 MCH 23.0 - 33.0 MCHC 28.0 - 30.0 RDW% 11.7 - 15.0 PLT 140 - 440 MPV 8.0 - 11.0 3. The laboratory was asked to provide documentation of verifying the patient normal

ranges currently in use. No documentation was provided. 4. An interview with the technical consultant on 10/11/2018 at 11036 hour in the office- after his review of the records - confirmed the findings. KEY WBC - white blood cell LYM - lymphocytes MID - monocytes and basophils GRAN - granulocytes LYM% - percent lymphocytes MID% - percent monocytes and basophils GRA% - percent granulocytes RBC - red blood cell HGB - hemoglobin HCT - hematocrit MCV - mean corpuscular volume MCH - mean corpuscular hemoglobin MCHC - mean corpuscular hemoglobin concentration RDW% - red blood cell distribution width PLT - platelet MPV - mean platelet volume

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 the laboratory's verification records for the Medonic M-series hematology analyzer, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing competency assessments prior to testing personnel performing patient testing. The findings were: 1. A review of the laboratory's verification records for the Medonic M-series hematology analyzer revealed the laboratory was placed into use on October 9, 2017. 2. A review of the laboratory's personnel records revealed the technical consultant had performed competency assessments for testing personnel for hematology testing the following date: a) Testing personnel number 1 10/04/2017 09/18/2018 b) Testing personnel number 2 10/04/2017 09/18/2018 c) Testing personnel number 3 07/03/2017 07/07/2018 3. The laboratory was asked to provide documentation of the technical consultant performing competency assessments prior to testing personnel performing patient testing. No documentation was provided. 4. An interview with the technical consultant on 10/11/2018 at 1040 hours in the office revealed he was unaware competency assessments were required prior to testing personnel performing testing on a newly installed analyzer. This confirmed the findings.