

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0316415	(X3) Date Survey Completed 10/04/2022
Name of Provider or Supplier Pravinchandra P Patel Mdpc	Street Address, City, State 431 Central Ave, Coldwater, MS	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Cell Dyn Emerald QC (quality control) records from 3/10/2021 through 10/4/2022 and confirmation with TP #1 at 4:00 p.m., the laboratory failed to retain the QC assay sheets for each lot used. QC assay sheets include acceptable ranges, storage requirements, lot numbers and standard deviations and should be kept for a minimum of 2 years. Findings include: 1. Review of the Cell Dyn Emerald QC records indicated that QC lot #1319 was in use on the day of the survey. 2. Review of the Cell Dyn Emerald QC records from 03/10/2021 until 10/4/2022, revealed the following hematology QC lots had been used and no assay sheets retained. a. Cell Dyn QC lot #2038 low, normal, high b. Cell Dyn QC lot #2122 low, normal, high c. Cell Dyn QC lot #2206 low, normal, high d. Cell Dyn QC lot #1067 low, normal, high e. Cell Dyn QC lot #1151 low, normal, high 3. Interview with the TP #1 at 4:00 p.m. on 10/04/2022 confirmed the lab did not retain all QC assay sheets with the change of each lot number of QC material for the Cell Dyn Emerald hematology analyzer.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if</p>

applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of laboratory records since 03/10/2021 and confirmation with the laboratory director/technical consultant (LD/TC) and TP #1 and #3 at 6:00 p.m. on 10/04/2022, the laboratory failed to monitor and document the room temperature where hematology testing was performed. Findings include: 1. Observation of the laboratory room where hematology testing was performed revealed no thermometer to monitor the room temperature for optimal performance of the Cell Dyn Emerald hematology analyzer. 2. Cell Dyn Emerald manufacturer's instructions require: a) The Cell Dyn Emerald reagent, lyse and detergent should be stored at a temperature range of 18-32 degrees Celsius (C). b) Operating specifications for the Cell Emerald hematology analyzer require a room temperature of 18- 32 degrees C. c) Quality control and calibration materials for the Cell Dyn Emerald must be allowed to come to room temperature before testing. 3. Interview with the LD/TC, TP#1, and TP#3 at 6:00 p.m. on 10/04/2022 confirmed no room temperatures were being monitored and documented.

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on review of the Cell Dyn Emerald hematology calibration records from 03/10/2021 through 10/04/2022 and interview with TP #1 and TP #3 at 3:30 p.m. on 10/04/2022, the laboratory failed to perform calibration on the Cell Dyn Emerald hematology analyzer every 6 months as required by the manufacturer. Findings include: 1. Review of the Cell Dyn Emerald calibration records revealed calibration was performed on 03/12/2021, 9/30/2022 and 10/04/2022. These calibration time frames exceed the 6 month mandatory calibration requirement of manufacturer. 2. Interview with the TP #1 and TP# 3 3:30 p.m. on 10/04/2022 confirmed CBC calibrations were not performed every 6 months.

D6017

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of the laboratory proficiency testing (PT) records, the Centers for Medicare and Medicaid Services (CMS) proficiency data system report (CASPER 0155D), and interview with TP#1 at 5:30 p.m. on 10/04/2022, the laboratory director failed to ensure that results were returned within the timeframe established by the proficiency testing program for the 3rd event of 2021. Findings include: 1. Based on review of the proficiency records and the CMS proficiency data base--CASPER report 0155D, the laboratory performed the 3rd event of proficiency testing for CBC (complete blood count) but results were not submitted in time to be graded for participation. The PT event was graded as 0% for nonparticipation. 2. Interview with TP #1 at 5:30 p.m. on 10/04/2022 confirmed the proficiency samples were tested but were not returned within the timeframe in order to be graded.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of laboratory testing records from 03/10/2021 through 10/04/2022 and interview with the LD/TC, TP #1 and #3 at 6:00 p.m. on 10/04/2022, maintenance, QC (quality control), calibration, temperature and proficiency records listed below had not been documented as reviewed by the technical consultant (TC). Findings Include: 1. Review of the laboratory records from 03/10/2021 through 10/04/2022 revealed the following records were not documented as reviewed by the TC: a. Cell Dyn Emerald hematology maintenance records from 3/25/2021 through 10/4/2022 b. Temperature records (refrigerator, freezer) from 03/22/2021 through 10/04/2022 c. Cell Dyn Emerald hematology QC records from 03/25/2021 through 10/04/2022 d. Cell Dyn Emerald hematology calibration on 03/12/2021 and 09/30/2022 e. Proficiency records (1st and 3rd events of 2021 and 1st and 2nd events of 2022) 2. Interview with the LD/TC, TP #1 and TP #3 at 6:00 p.m. on 10/04/2022 confirmed there was no documented review of these records by the TC during this time period.

D6054

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 at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of laboratory testing personnel (TP) records including the Centers of Medicare and Medicaid Services (CMS) 209 personnel form and interview with the laboratory director (LD) and TP#1, the technical consultant failed to evaluate annually

and document the performance of testing personnel #2 who is responsible for performing moderate CBC (complete blood count) testing. Findings include: 1. Based on laboratory personnel records available for review on the day of survey, there was no annual evaluation/competency performed by the technical consultant on TP #2 since 01/13/2021. 2. Interview with the LD and TP #1, #2 and #3 on 10/04/2022 at 5:30 p.m. confirmed no annual evaluation/competency for TP #2 had been documented as performed by the technical consultant for 2022.