

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0303442	(X3) Date Survey Completed 02/03/2022
Name of Provider or Supplier Northeast Al Peds	Street Address, City, State 829 Riverbend Drive, Gadsden, AL	
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
D2021	<p>BACTERIOLOGY CFR(s): 493.823(b)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to submit proficiency testing results by the submission deadlines for Microbiology - Throat Cultures testing for Event #2 2020 and Event #3 2021. The laboratory scored zero percent (0%) for these events, due to the failure to timely submit the results. This affected two of seven Microbiology PT events reviewed by the surveyor. The findings include: 1. A review of the PT records revealed the due date to submit API proficiency testing results for the Event #2 2020 was 07/06/2020. The API Performance Summary for Event #2 2020 revealed zero percent (0%) for Throat Culture failure to participate. 2. A review of the PT records revealed the due date to submit API proficiency testing results for the Event #3 2021 was 10/13/2021. The API Performance Summary for Event #3 2021 revealed zero percent (0%) for Throat Culture failure to participate. 3. During an interview on 02/03/2022 at 10:53 AM, Testing Personnel #1 confirmed Event #2 2020 due date was overlooked, and Event #3 2021 arrived while she was out sick. The two new employees did not see the PT in time to perform before the due date. Also, Testing Personnel #1 confirmed</p>

patient testing was being performed during these time periods, when staff failed to perform proficiency testing.

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 a review of the Medonic M-series calibration records, Medonic M-series User's Manual, and interview with Testing Personnel #1, the laboratory failed to calibrate the Micro Pipette Adapter (MPA) on the Medonic M-series which is the mode patient testing was being performed. This was noted from previous survey (September 2019) to current survey (February 2022), and affected four calibrations. The findings include: 1. A review of the Medonic M-series calibration records revealed the laboratory performed calibration for the Open Tube mode on 3/10/2020, 09/17/2020, 2/08/2021, and 8/20/2021. The last calibration log on 08/20/2021 revealed the MPA was last calibrated on 09/06/2018. 2. A review of the Medonic M-series User's Manual revealed on page 62 "...To calibrate MPA follow Steps 1-17 above except select [CALIBRATION] and then choose [CAPILLARY DEVICE] instead of Whole Blood Calibration in Step 6 and use MPA mode for analysis." 3. During an interview on 02/03/2022 at 11:45 AM, Testing Personnel #1 confirmed all patient samples are run in the MPA mode and calibration was being done in the Open Tube Mode.

D5471

CONTROL PROCEDURES

CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the Bacteriology Quality Control (QC), and an interview with Testing Personnel #1, the laboratory failed to document acceptable quality control results for negative Bacitracin ("A" disc) QC. This was noted from 09/05/2021 to 01/20/2022, the surveyor reviewed from 09/23/2019 to 01/20/2022. This is a repeat citation. The findings include: 1. A review of the Bacteriology records revealed from

09/05/2021 to 01/20/2022 the QC for Bacitracin was performed six times. During these six times the Streptococcus Agalactiae (negative control) was documented as "no growth up to disk". 2. During an interview on 02/03/2022 at 2:00 PM, Testing Personnel #1 stated she documented incorrectly for the negative Bacitracin QC because she had to re-document due to coffee being spilled on the originals. The surveyor asked why the form submitted as corrective action from the previous survey was not being used, and Testing Personnel #1 had forgot about the form.

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of the Hematology quality control (QC) records for the Medonic, the patient logs, and an interview with Testing Personnel #1, the laboratory failed to ensure at least two levels of quality control were run and acceptable, prior to analyzing patient specimens and reporting the results. This was noted five days out of nine months reviewed from November 2019 to November 2021 by the surveyor. The findings include: 1. A review of the QC records for the Medonic Hematology analyzer revealed a) on 06/13/2020 hemoglobin was outside of acceptable limits for normal and high control b) on 06/14/2020 hemoglobin was outside of acceptable limits for normal and high control c) on 10/25/2020 hemoglobin was outside of acceptable limits for low and high control d) on 02/12/2021 no low, normal, or high control were run e) on 05/22/2021 hemoglobin was outside of acceptable limits for normal and high control. 2. A review of the patient logs revealed a) on 06/13/2020 3 patient tests were run b) on 06/14/2020 2 patient tests were run c) on 10/25/2020 6 patient tests were run d) on 02/12/2021 12 patient tests were run e) on 05/22/2021 3 patient tests were run 3. During an interview on 02/03/2022 at 1:20 PM, Testing Personnel #1 confirmed the above findings.

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 the review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the surveyor determined the laboratory director failed to ensure PT results were returned within the timeframes established by API for Microbiology - Throat Cultures testing for Event #2 2020 and Event #3 2021. The laboratory scored zero percent (0%) for these events, due to the failure to timely submit the results. This affected two of seven Microbiology PT events reviewed by the surveyor. The findings include: 1. Refer to D2021.