

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2153232	(X3) Date Survey Completed 01/05/2022
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 2017 S College St Ste C, Trenton, 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
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 observation of the laboratory, review of laboratory records and staff interview, the laboratory failed to retain complete blood count (CBC) quality control (QC) limits for two years for 27 of 42 lots. The findings include: 1. Observation of the laboratory on January 5, 2022 at approximately 10:15 am revealed the Sysmex XS 1000iC (serial number A1055) in use for patient testing for CBC. 2. Review of the laboratory's CBC QC records revealed no retention of the QC limits for 27 of 42 lots surveyed. Lot numbers affected are 93230804, 93230805, 93230806, 00140804, 00140805, 00140806, 00700804, 00700805, 00700806, 01260804, 01260805, 01260806, 01820804, 01820805, 01820806, 02380804, 02380805, 02380806, 02940804, 02940805, 02940806, 03500804, 03500805, 03500806, 10400804, 10400805, and 10400806. The lots were in use from January 6, 2020 until April 30, 2021 with patient testing performed. 3. Interview with the laboratory supervisor on January 5, 2022 at approximately 5:00 pm confirmed the laboratory failed to retain quality control limits for 27 of 42 lots in 2020 and 2021. The supervisor further confirmed that patient testing was performed during the entire period.</p>
D5024	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p>

This CONDITION is not met as evidenced by:
The laboratory failed to follow the procedure for entry of complete blood count quality control ranges (Refer to D5401) and failed to have an effective quality assessment process for detecting errors in complete blood count quality control (Refer to D5793).

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:
Based on observation of the laboratory, review of the laboratory procedure manual, laboratory quality control (QC) records, and staff interview, the laboratory failed to follow the procedure for entry of quality control limits for complete blood count (CBC) for six of fifteen lots in 2021 and 2022. The findings include: 1. Observation of the laboratory on January 5, 2022 at approximately 10:15 am revealed the Sysmex XS1000iC (serial number A1055) in use for patient CBC testing. 2. Review of the laboratory's procedure titled "Sysmex XS-1000 Series Quality Control" revealed the following: "Sysmex uses 'Limit Range %' as a part of the QC process in the XS-1000 Series instrument. Sysmex recommends that the Limit Range % be set in accordance with the Sysmex Evidence-Based Control Limits." "This model-specific limit %'s will be entered and verified as recommended." 3. Review of the laboratory's QC records for lot numbers 12640804-level one, 12640805-level two, 12640806- level three, 13200804-level one, 13200805-level two, and 13200806-level three revealed the laboratory did not enter the Limit Range % when setting up the new QC lot numbers, resulting in the use of incorrect quality control limits from October 7, 2021 until January 5, 2022 for all parameters. Approximately 120 patients were reported during the period when the incorrect QC limits were in use. See below for selected parameters for incorrect ranges for red blood cell (RBC), white blood cell (WBC), Hematocrit (HCT), Hemoglobin (HGB) and Platelet (PLT): Lot 1264--Previous Lot Package insert Range used RBC Level 1 2.23-2.46 0.0-4.68 RBC Level 2 4.15-4.50 0.0-8.62 RBC Level 3 4.95-5.36 0.0-11.8 WBC Level 1 2.65-3.31 0.0-5.88 WBC Level 2 6.31-7.55 0.0-13.98 WBC Level 3 15.21-17.85 0.0-32.38 HCT Level 1 17.3-19.9 0.0-36.4 HCT Level 2 36.0-40.6 0.0-76.2 HCT Level 3 45.2-50.9 0.0-95.6 HGB Level 1 5.6-6.3 0.0-11.6 HGB Level 2 12.2-13.3 0.0-25.4 HGB Level 3 15.5-16.8 0.0-32.2 PLT Level 1 42-76 0-120 PLT Level 2 202-257 0-468 PLT Level 3 490-599 0-1108 Lot 1320--Current Lot Package insert Range used RBC Level 1 2.25-2.48 0.0-4.66 RBC Level 2 4.19-4.54 0.0-8.64 RBC Level 3 5.00-5.42 0.0-10.36 WBC Level 1 2.66-3.32 0.0-5.98 WBC Level 2 6.23-7.46 0.0-13.84 WBC Level 3 14.73-17.3 0.0-32.38 HCT Level 1 16.9-19.4 0.0-36.4 HCT Level 2 35.0-39.5 0.0-74.6 HCT Level 3 45-50.7 0.0-96.2 HGB Level 1 5.5-6.2 0.0-11.6 HGB Level 2 12.1-13.1 0.0-25.0 HGB Level 3 15.7-17.0 0.0-32.6 PLT Level 1 44-79 0-118 PLT Level 2 205-261 0-464 PLT Level 3 488-597 0-1088 4. Interview with the laboratory supervisor on January 5, 2022 at approximately 5pm confirmed the laboratory failed to follow the procedure for correct quality control limit setting for six of fifteen lots in 2021 and 2022.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the laboratory procedure manual, quality control records and interview with the laboratory supervisor, the laboratory's quality assessment program was ineffective at identifying and correcting problems with complete blood count (CBC) quality control in 2020, 2021 and 2022. The findings include: 1. Observation of the laboratory on January 5, 2022 at approximately 10:15 am revealed the Sysmex 1000iC on the counter in use for patient CBC testing. 2. Review of the laboratory's procedure manual revealed the following: The laboratory's CBC quality control procedure revealed the following statement "Daily QC reports will be printed, reviewed, and filed monthly. Period and cumulative reports will be printed, reviewed, and filed as they become available from the Sysmex Insight Program. The laboratory's quality assessment plan revealed the following statement "LabCorp has a planned and systematic process for monitoring and evaluating the quality and appropriateness of patient care and for resolving identified problems to improve the quality of the laboratory." 3. Review of laboratory CBC QC records revealed no retention of CBC QC limits from January 6, 2020 to April 30, 2021 (Refer to D3031) and incorrect QC limits in use from October 18, 2021 until January 5, 2022 (Refer to D5401). No evidence of corrective action for the lack of retention of CBC QC limits or the use of incorrect CBC QC limits was noted. 5. Interview with the laboratory supervisor on January 5, 2022 at approximately 5:00 pm confirmed the laboratory's quality assessment program was ineffective at identifying and correcting problems with retention of QC limits and the use of incorrect QC limits in 2020 and 2021 when it used Sysmex Insight reports for quality control data retention and final review.