

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1022793	(X3) Date Survey Completed 06/07/2023
Name of Provider or Supplier Creative Testing Solutions	Street Address, City, State 5700 Pleasant View Road, Memphis, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing records and staff interview, the laboratory failed to ensure eight of seventy-five proficiency testing attestation statements from 2020, 2021, 2022, and 2023 were signed by the lab director or designee. The findings include: 1. Review of the laboratory's CAP proficiency testing records revealed the following attestation statements from 2022 that had not been signed by either the lab director or designee: Transfusion Medicine (Comp) J-A 2022 Transfusion Medicine (Automated) JAT-A 2022 Electrophoresis ELP-B 2022 Sickle Cell Screening SCS-B 2022 Red Blood Cell Antigen Typing RBCAT-B 2022 Nucleic Acid Testing NAT-B 2022 Infectious Disease Serology VR3-B 2022 Syphilis Serology G-C 2022 2. Interview with the quality manager on 06/07/23 at 1:40 pm confirmed the survey findings.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records, lack of records, review of personnel policies,</p>

and interview with the quality manager, the laboratory's personnel policy failed to be in compliance with the personnel regulations in Subpart M when it did not include a requirement for technical consultant, technical supervisor or general supervisor competency assessments. The findings include: 1. Review of personnel records revealed the following: Job description and delegation of lab director duties for technical consultant, technical supervisor and general supervisor to two persons. 2. No competency assessment for either of the two personnel who were delegated the duties of technical supervisor, general supervisor and technical consultant were available. 3. Review of the laboratory personnel policy revealed consultant/supervisor competency was not included as a requirement. 4. Interview with the quality manager on 06/07/23 at 1:40 pm confirmed the laboratory failed to have a policy that was in compliance with Subpart M when it did not include consultant/supervisor competency in its' personnel policies.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of the laboratory inhouse test menu, lack of records, staff interview, and email communication, the laboratory failed to verify the accuracy of the Parvo B-19 and Hepatitis A virus testing twice a year in 2021 and 2022 with approximately 2,544,234 tests performed. The findings include: 1. Observation of the laboratory on 06/05/23 at 12:00 pm revealed the Grifols Procleix Panther system in use for performing Parvo B-19 and Hepatitis A virus testing. 2. Review of the laboratory inhouse test menu revealed the laboratory began testing on plasma donors for Parvo B-19 and Hepatitis A virus in August 2020. 3. No records for twice a year verification of accuracy were available on the date of the survey for 2021 and 2022. 4. Interview with the quality manager on 06/07/23 at 1:40 pm confirmed the laboratory failed to verify the accuracy of the Parvo B-19 and Hepatitis A testing performed on the Grifols Procleix Panther twice a year in 2021 and 2022. 5. Email communication with the quality manager on 06/16/23 at 9:02 am revealed the laboratory performed a total of approximately 2,544,234 tests for Parvo B-19 and Hepatitis A virus in 2021 and 2022.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected

by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of manufacturer package inserts, laboratory records and lack of records, test volumes and interview with the quality manager, the laboratory failed to perform calibration verification for the Alanine Transaminase (ALT) in 2023 and failed to perform calibration verification for the total protein in 2020, 2021, 2022, and 2023, with approximately 156, 683 donor tests for ALT performed during the gap in calibration verification and approximately 446,859 total protein donor tests performed. The findings include: 1. Observation of the laboratory on 06/05/23 at 12:00 pm revealed the Abbott Architect in use for performing ALT and the Roche Cobas in use for performing total protein. 2. Review of the manufacturer package inserts revealed the following: Calibration of the ALT is performed using one calibration point with water. Calibration of the Total Protein is performed using two calibration points. 3. Review of laboratory records revealed the following: Verification of calibration for the ALT was last performed during test validation on 09/21/22. The laboratory began donor testing for ALT on 02/04/23. No six month calibration verification for the ALT had been performed. Calibration verification for the Total Protein was last performed during install/validation on 02/10/20. No six month calibration verification documents were available for 2020, 2021, 2022, and 2023. 4. Information provided by the quality manager revealed the following test volumes during the periods when calibration verification was not performed: ALT--Donor ALT performed from 03/21/23 to the date of the survey on 06/07/23 was 156,683. Total Protein--Donor numbers tested in 2020, 2021, 2022, and 2023 were 446,859. 5. Interview with the quality manager on 06/07/23 at 1:40 pm confirmed the laboratory failed to perform six month calibration verification for the ALT performed on the Abbott Architect in 2023 and Total Protein performed on the Roche Cobas in 2020, 2021, 2022, and 2023.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and staff interview during observation, lack of records, and interview with the quality manager, the laboratory failed to perform instrument to instrument, and method to method comparison twice a year for multiple instruments and test methods in use in 2020, 2021, 2022 and 2023. The findings include: 1. Observation of the laboratory on 06/05/23 at 12:00 pm and staff interview during observation revealed the following multiple instruments and test methods in

use that perform the same tests: Alanine Transaminase (ALT) performed on the Abbott Architect (C804904 and C804905). Syphilis testing performed on the ASI Evolution (instrument #s 2009, 1009, 1014, and 1013). Chagas and Hepatitis B Core Antibody performed on the Abbott Alinity S (instrument numbers AS1347 and AS1348.) Three Erytra instruments in use for performing ABO, Rhesus Factor (Rh), Rh Phenotype, and Kell antigen typing (instrument numbers 0991, 1444, 1678). Staff interview during the observation revealed that the laboratory also uses a manual gel method to verify the ABO if there is a discrepancy on the Erytra. 2. No records were available for twice a year comparison as follows: ALT performed on the Abbott Architect for 2023. Syphilis testing performed on the ASI Evolution multiple instruments in 2020, 2021, 2022, or 2023. Chagas and Hepatitis B Core antibody for 2022 or 2023. ABO, Rh, Rh Phenotype, and Kell antigen typing performed on multiple Erytra instruments in 2020, 2021, 2022 or 2023. Manual and automated ABO determination in 2020, 2021, 2022, and 2023. 3. Interview with the quality manager on 06/07/23 at 1:40 pm confirmed the survey findings.