

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0677246	(X3) Date Survey Completed 06/02/2022
Name of Provider or Supplier Memphis Childrens Clinic	Street Address, City, State 1129 Hale 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
D0000	493.51 Notification requirements for laboratories issued a certificate of compliance Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in-- (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity only). (b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory ' s certificate of compliance, so that compliance with requirements can be determined. (c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance. This requirement is not met as evidenced by: Based on review of the laboratory's specialties in the Aspen Web 116, observation of the laboratory, review of the Centers for Medicare and Medicaid Services Application for Certification (Form CMS-116), request for documentation, and interview with the lead testing person, the laboratory failed to notify the State Agency of change in specialties within six months of the change. The findings include: 1. Review of the laboratory' specialties in the Aspen Web 116 revealed the specialty of bacteriology. 2. Observation of the laboratory on 06 /02/2022 at 8:30 am revealed no evidence of testing in the specialty of bacteriology. 3. Review of the laboratory's Form CMS-116 completed as part of the survey revealed bacteriology was not listed as a specialty. 4. Request on 06/02/2022 at 9:30 am for documentation of State Agency notification of change in specialties revealed no documentation was available. 5. Interview with the lead testing person on 06/02/2022 at 9:30 am confirmed the laboratory had ceased testing for the bacteriology specialty. She was unsure, but believed it was sometime in 2019. She further confirmed notification there was no documentation the State Agency had been notified of the change. The laboratory failed to notify the State Agency of change in specialties within six months of the change.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's American Proficiency Institute (API) proficiency testing attestation statements and interview with the lead testing person, the laboratory director and testing personnel failed to sign attestation statements for four of six proficiency testing events reviewed in 2020, 2021 and 2022. The findings include: 1. Review of the laboratory's API Hematology/Coagulation proficiency testing attestation statements revealed attestation statements that were not signed by the lab director/testing personnel as follows: Not signed by lab director: 2020 event three, 2021 event one Not signed by testing personnel: 2021 event two and 2022 event one 2. Interview with the lead testing person on 06/02/2022 at 1pm confirmed four of six proficiency testing attestation statements were either not signed by the lab director or the testing personnel in 2020, 2021, and 2022.

D3011

FACILITIES

CFR(s): 493.1101(d)

Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and interview with the lead testing person, the laboratory failed to protect its' patient from potential biological hazards when it stored patient medication in the same refrigerator as quality control vials and patient blood samples in 2022. The findings include: 1. Observation on 06/02/2022 at 8:30 am of the laboratory refrigerator revealed the storage of over-the-counter children's medication in the same refrigerator as quality control vials and patient blood samples. 2. Interview with the lead testing person on 06/02/2022 at 1 pm confirmed the laboratory failed to ensure its' patients were protected from biological hazards when it stored patient medications in the same refrigerator with quality control material and patient specimens in 2022.

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 patient test reports, document request, and interview with the lead testing person, the laboratory failed to have a written procedure for use of the Sysmex SN-330 Complete Blood Count instrument beginning 04/07/2022 until survey date on 06/02/2022. The findings include: 1. Observation of the laboratory on 06/02/2022 at 8:30 am revealed the Sysmex SN-330

CBC instrument (serial #14731) on the counter in use for performing patient complete blood count (CBC) testing. 2. Review of the first patient reported (patient #2) revealed patient testing began on 04/07/2022. 3. Request made to the lead testing person on 06/02/2022 at 11:30 am for Sysmex XN-330 instrument procedure manual revealed no written and approved procedure was available. 4. Interview with the lead testing person on 06/02/2022 at 2 pm confirmed the laboratory began patient testing for CBC on 04/07/2022 until the date of the survey on the Sysmex XN-330 without a written procedure for use.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of manufacturer complete blood count (CBC) quality control package insert and interview with the lead testing person, the laboratory failed to label complete blood count quality control vials with open date and corrected expiration date on the date of the survey (06/02/2022). The findings include: 1. Observation of the laboratory on 06/02/2022 at 8:30 am revealed the Sysmex XN-330 CBC instrument (serial #14731) in use for patient testing. Observation of the control vials in use revealed no labeling to indicate when they were opened or the corrected expiration date. 2. Review of the manufacturer quality control package insert revealed the following statement: "Open vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored at 2-8 degrees C after being re-capped." 3. Interview with the lead testing person on 06/02/2022 at 1 pm confirmed the laboratory had not labeled CBC quality control vials with open date and corrected expiration date on the date of the survey (06/02/2022).

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records and interview with the lead testing person, the laboratory director failed to review one of six proficiency testing performance evaluation reports in 2021. The findings include: 1. Review of the laboratory's API Hematology/Coagulation proficiency testing performance evaluation report for 2021 event three revealed the report had not been reviewed by the laboratory director. 2. Interview with the lead

testing person on 06/02/2022 at 1pm confirmed the laboratory director failed to review 2021 event three proficiency testing evaluation report (one of six reviewed) in 2021.