

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0931690	(X3) Date Survey Completed 06/25/2024
Name of Provider or Supplier Abc Pediatrics	Street Address, City, State 3675 Boca Chica Blvd Suite E, Brownsville, TX	
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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
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 laboratory's policy, manufacturer's quality control (QC) package inserts and confirmed in interview, the laboratory failed to retain manufacturers' QC package inserts for six of six lot numbers on the Sysmex XN-L hematology analyzer from September 2023 to May 2024. Findings include: 1. Review of the laboratory's policy titled "CONTROL POLICY" approved by the laboratory director on 02/26/1998 stated: "...records kept for at least two years." 2. Review of historical QC data for the Sysmex XN-L hematology analyzer from September 2023 to May 2024 determined the following QC lots were used by the laboratory: a) Master lot: 232314 b) Master lot: 304214 c) Master lot: 312614 d) Master lot: 321014 e) Master lot: 329414 f) Master lot: 401314 3. The laboratory was asked to provide manufacturer's package inserts for listed lots. On 06/24/2024 at 1042 hours in room 10, testing person-1 stated the laboratory does not have the package inserts for previous QC lots in use. 4. Testing person-1 and the technical consultant confirmed the findings in an interview on 06/24/2024 at 1043 hours in room 10.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory</p>

must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's maintenance logs from December 2023 to May 2024, and confirmed in interview, the laboratory failed to document monthly maintenance five of six months, and quarterly maintenance for one of two months for the Cepheid GeneXpert Xpress analyzer. Findings include: 1. Review of the laboratory's maintenance logs titled "GeneXpert Xpress System Maintenance Log" (302-5611 Rev. D August 2023) from December 2023 to May 2024 determined manufacturer-specified monthly maintenance was not documented on the following months: a) December 2023 b) February 2024 c) March 2024 d) April 2024 e) May 2024 Further review of the laboratory's maintenance logs determined manufacturer-specified quarterly maintenance was required on the following months: a) February 2024 (documented) b) May 2024 (not documented) 2. The technical consultant confirmed the findings during an interview on 06/25/2024 at 1303 hours in room 10.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid (CMS)-209 form, review of the laboratory's competency documentation, and confirmed in interview, the laboratory failed to ensure two semi-annual competency assessments were documented within the first year of training for two of two testing personnel performing moderate complexity testing. Findings include: 1. Review of the CMS-209 form determined testing person-3 and testing person-4 were listed as testing personnel performing moderate complexity testing. 2. Review of the laboratory's training and competency documentation determined: a) Testing person-3: Training date: 11/03/2021 Semi-annual competency: 03/14/2022 (4 months, 12 days from training) Semi-annual competency: 03/07/2023 (1 year, 4 months, 5 days from training) b) Testing person-4: Training date: 08/18/2022 Semi-annual competency: 10/28/2022 (2 months, 11 days from training) Semi-annual competency: 11/21/2023 (1 year, 3 months, 4 days from training) 3. The technical consultant confirmed the findings in an interview on 06/25/2024 at 0950 hours in room 10.