

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1017251	(X3) Date Survey Completed 09/23/2021
Name of Provider or Supplier Children's Healthcare Center	Street Address, City, State 3145 West Alberta, Edinburg, 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 surveyed and found to be in compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended.
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's American Proficiency Institute (API) proficiency testing records, and confirmed in interview of facility personnel, the laboratory failed to have documentation of testing proficiency testing samples the same as it tests patients for two of five testing events. The findings were: 1. Review of the laboratory's proficiency testing policy approved by the laboratory director on December 13, 2011 stated, "PT specimens are to be treated the same as patient samples..." 2. Review of the laboratory's proficiency testing (PT) records from 2019 (event 3), 2020, (events 1, 2, and 3), and 2021 (event 2) found the two people tested each sample on the same day. 2019 -event 3 HSY-11 tested by same person twice (no repeat criteria met) 2021-event 2 HSY-11 tested by two people on same day HSY-12 tested by two people on same day HSY-13 tested by two people on same day</p>

HSY-14 tested by two people on same day HSY-15 tested by two people on same day
3. An interview with the Technical Consultant on September 23, 2021 at 10:45 hours in the laboratory confirmed the findings.

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 (PT) records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of the laboratory director signing one of five attestation statements. The findings included: 1. Review of proficiency testing instructions from API under "Signatures Required" it stated, "Testing personnel and the laboratory director must physically sign an attestation statement for all PT results, and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." 2. Review of the laboratory's API proficiency testing records from 2019 (event 3), 2020 (events 1, 2, and 3), and 2021 (event 2) found the laboratory director and testing person failed to sign the following attestation sheet. 2021 (event 2) 3. An interview with the Technical Consultant on September 23, 2021 at 10:30 hours in the laboratory confirmed the findings.