

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0966858	(X3) Date Survey Completed 03/24/2022
Name of Provider or Supplier Pinnacle Healthcare Pllc DbA Mission Kids Clinic	Street Address, City, State 1616 N Conway Ave, Mission, 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	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Academy of Bioanalysts (AAB) proficiency testing (PT) records from 2020 (event 3) and 2021 (events 1, 2, and 3), review of the laboratory's policies, and staff interview, found the laboratory failed to have documentation of testing proficiency samples the same number of times as patient samples for 2 of 4 proficiency testing events reviewed. The findings included: 1. A review of the laboratory's policy titled, 'Proficiency Testing Program' approved by the laboratory director on March 21, 2022 stated, " ...3. The usual laboratory verification procedures for PT survey samples will be followed where specified or applicable for patient samples. Replicate testing is allowed only if patient specimens are analyzed in this manner when Panic Values are reporting or if the Laboratory</p>

Director requests repeat testing." 2. A review of the laboratory's policy titled 'CBC with Flags Action Policy' approved by the laboratory director on March 21, 2022 stated, " ...Verify results by repeat testing on same sample which revealed the flags BD, NM, OM, and TM." 3. A review of the laboratory's AAB proficiency testing records from 2020 (event 3) and 2021 (events 1, 2, and 3) identified the following proficiency testing samples for which results were either repeated unnecessarily or not repeated according to the laboratory's own policy: 2020 (event 3) Sample 12 Flag: TM Not repeated 2021 (event 3) Sample 12 No criteria met Tested on 10/20/2021 @17:06 Repeat testing on 10/20/2021 @17:08 2021 (event 3) Sample 14 No criteria met Tested on 10/20/2021 @17:11 Repeat testing on 10/20/2021 @17:13 4. An interview with the primary testing person on March 24, 2022 at 10:05 hours in the break room - after her review of the records- confirmed the findings. Key: CBC - complete blood count