

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0966858	(X3) Date Survey Completed 05/13/2026
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	The laboratory was found to be out of compliance with 42 CFR Part 493, Requirements for Laboratories following a scheduled recertification survey completed on 05/13/2026. The following condition was not met: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel
D5813	<p>TEST REPORT CFR(s): 493.1291(g)</p> <p>(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of patient test records from March 2026, and interview with staff, the laboratory failed to have documentation of the notification of 1 of 1 panic values. The findings included: 1. The laboratory's policy titled "Repeat and Panic Value Policy" under the section titled "Policy" stated: "When a critical value is noted it will be verified by repeating the test and the result will be called or given to the Physician with 15-30 minutes. Document on the patient's report the date, time and provider receiving the panic value." 2. The policy defined the following panic values: White Blood Cell: 2. 0 - 37.00 5.0 - 30.00 3. A review of patient test records from March 2026 identified one patient result with a panic value. It was: a) Sequence number: 3963 WBC: 1.2 Sequence number: 3963 WBC: 1.7 4. The patient results did not have documentation of the panic value, the notification of the physician of the panic value, and the date/time of the notification. 5. The technical consultant confirmed the findings in an interview conducted on 05/13/2026 at 10:00 am in the break room.</p>
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's submitted CMS 209, review of the laboratory's personnel records, and interview with staff, the laboratory failed to have documentation of training on the Medonic M-series hematology analyzer for 2 of 3 testing personnel (refer to D6066).

D6066

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(4)(ii)

(b)(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has-

- (b)(6)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens;
- (b)(6)(ii)(B) The skills required for implementing all standard laboratory procedures;
- (b)(6)(ii)(C) The skills required for performing each test method and for proper instrument use;
- (b)(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;
- (b)(6)(ii)(E) A working knowledge of reagent stability and storage;
- (b)(6)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory;
- (b)(6)(ii)(G) An awareness of the factors that influence test results; and
- (b)(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted CMS 209, review of the laboratory's personnel records, and interview with staff, the laboratory failed to have documentation of training on the Medonic M-series hematology analyzer for 2 of 3 testing personnel. The findings included:

1. A review of the laboratory's submitted Form CMS 209 determined the laboratory identified 3 personnel who performed moderate complexity testing on the Medonic M-series hematology analyzer.
2. A review of the laboratory's personnel records determined the laboratory failed to have documentation of training on the Medonic M-series analyzer for 2 of 3 personnel. They were: a) Testing personnel number 2 Education: High school diploma Start date: 9/2025 b) Testing personnel number 3 Education: High school diploma Start date: 8/25 3. The technical consultant confirmed the findings in an interview conducted on 05/13/2026 at 9:00 am in the break room.