

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0117604	(X3) Date Survey Completed 03/04/2025
Name of Provider or Supplier Minniti Center For	Street Address, City, State 174 Democrat Road, Mickleton, NJ	
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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to verify the accuracy of PT results obtained from the Wisconsin State Laboratory of Hygiene (WSLH) for the third Hematology event in 2024 from 11/14/24 to 3/4/25. The finding includes: 1. The laboratory received a score of 100% for the analytes Hemoglobin and Hematocrit % for samples AT-11,12,13,14 and 15 for the Third Hematology event in 2024 2. The results stated "not scored- insufficient peer group." 3. The WSLH PT report states "Federal regulations require an automatic score of 100% for not scored or non-consensus samples, but this may not be indicative of instrument/method performance. Participants flagged as such must perform and document an internal self-evaluation to satisfy regulatory/accreditation requirements. 4. There was no documented evidence the laboratory performed and documented an internal self evaluation for the not scored samples by WSLH. 5. The TP #1 as listed on the CMS-209 form confirmed on 3/4/25 at 11:20 am, the accuracy of the PT results were not verified.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p>

This STANDARD is not met as evidenced by:
Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to document the evaluation of all unsatisfactory PT scores and corrective action taken for PT performed with Wisconsin State Laboratory of Hygiene (WSLH) for the Third Hematology event in 2024 from 11/14/24 to 3/4/25. The finding includes: The findings include: 1. The laboratory received a failing score for sample AT-14. 2. There was no documented evidence for evaluation or corrective action performed for sample AT-14. 3. The TP #1 as listed on the CMS-209 form confirmed on 3/4/25 at 11:15 am, the laboratory failed to evaluate and perform corrective action for the Third Hematology event of 2024.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to establish corrective action procedures for Proficiency Testing (PT) from 6/28/23 to 3/4/25. The finding includes: 1. The laboratory did not establish a procedure that stated what corrective actions to take for unsatisfactory PT scores. 2. The laboratory did not establish a procedure that stated what corrective actions to take for non-scored PT results. 3. The TP #1 as listed on the CMS 209 form confirmed on 3/4/25 at 11:35 am, the laboratory did not establish corrective action procedures for PT.

D5409

PROCEDURE MANUAL
CFR(s): 493.1251(e)

(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to record discontinuance dates for all applicable procedures for the Beckman Coulter AcT Diff 2 analyzer from 8/1/24 to 3/4/25. The finding includes: 1. The PM did not have discontinuance dates for "Acceptable Reporting Procedure" and "Reporting Results Procedure" for the Beckman Coulter AcT Diff 2 which is no longer in use. 2. TP #1 as listed on the CMS-209 form confirmed on 3/4/25 at 11:45 am, discontinuance dates for all applicable procedures for the Beckman Coulter AcT Diff 2 analyzer were not documented.