

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2266950	(X3) Date Survey Completed 04/23/2024
Name of Provider or Supplier Angel Touch Nurse Registered, Llc	Street Address, City, State 13155 Sw 134 St Unit 119, Miami, FL	
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	An initial certification survey conducted at ANGEL TOUCH NURSE REGISTERED LLC on 04/23/2024 found the clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 Proficiency Testing (PT) records and procedure manual, and interview, the laboratory failed to treat PT samples in the same manner as patient samples for one out of one event reviewed for Chemistry specialty. Findings included: -Review of the laboratory Proficiency Testing policy signed by the Laboratory Director (LD) on 09/12/2023 revealed that stated on section "Procedures: A. Testing the Unknown Samples on point 2 stated: The PT samples must be handled exactly (as it is written) like patient specimens, utilizing usual testing methods, utilizing usual testing methods, instruments, and personnel. Repeated analysis of PT samples shall not be permitted unless the lab performs the same repetitive analysis in the routine analysis of routine patient specimens." -Review of American Proficiency Institute (API) PT records for Chemistry specialty for the first event of 2024 revealed the following: Samples CH-01, CH-02, CH-03, CH-05 results reported match with results from instrument printout on 01/25/2024 21:29:46 for the analytes: Alkaline</p>

Phosphatase, Alanine Transaminase (ALT), Aspartate Transferase (AST), Total Bilirubin, Cholesterol Total, Creatinine, Glucose, Total Protein, For analyte Carbon Dioxide (CO2), samples CH-01, CH-02, CH-03, CH-04, CH-05 were reported from results from instrument printout on 01/25/2024 21:29:46, this analyte was not run on 01/29/2024. For analytes: Cholesterol HDL and Triglycerides all results were reported from instrument printout on 01/29/2024 22:05:04, these analytes were not run on 01/25/2024. For Sample CH-04 Results reported to API for Alkaline Phosphatase: 136.00 Results from instrument printout on 01/25/2024 21:29:46: 130.00 Results from instrument printout on 01/29/2024 22:05:04: 136.00 Results reported to API for ALT: 15.00 Results from instrument printout on 01/25/2024 21:29:46: 15.00 Results from instrument printout on 01/29/2024 22:05:04: 15.00 Results reported to API for AST: 43.00 Results from instrument printout on 01/25/2024 21:29:46: 45.00 Results from instrument printout on 01/29/2024 22:05:04: 43.00 Results reported to API for Total Bilirubin: 0.4 Results from instrument printout on 01/25/2024 21:29:46: 0.43 Results from instrument printout on 01/29/2024 22:05:04: 0.42 Results reported to API for Calcium: 2.2 Results from instrument printout on 01/25/2024 21:29:46: 2.40 Results from instrument printout on 01/29/2024 22:05:04: 2.2 Results reported to API for Cholesterol Total: 189.00 Results from instrument printout on 01/25/2024 21:29:46: 194.00 Results from instrument printout on 01/29/2024 22:05:04: 189.00 Results reported to API for Glucose: 52.00 Results from instrument printout on 01/25/2024 21:29:46: 55.00 Results from instrument printout on 01/29/2024 22:05:04: 52.00 Results reported to API for Total Protein: 10.8 Results from instrument printout on 01/25/2024 21:29:46: 10.9 Results from instrument printout on 01/29/2024 22:05:04: 10.8 During an interview on 04/23/2024 at 10:30 AM, the technical consultant confirmed that the laboratory failed to run PT samples in the same manner as patient samples.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to perform at least two levels of quality control (QC) each day of patient testing on the Complete Blood Cell Counter (CBC) Sysmex XN-530 for one out of two testing days in January 2024. Findings included: -Review of General Quality Control policy signed by the Laboratory Director on 09/12/2023 revealed that on page 2 in Section "Laboratory Quality Control" noted "a minimum of two levels of quality control samples will be run prior and each day of patient testing." -Review of patient results revealed that on January 16, 2024, the laboratory tested 8 patients samples (P#1, P#2, P#3, P#4, P#5, P#6, P#7 and P#8). -Review of QC records revealed that the laboratory failed to run quality control samples before patient testing. During an interview on 04/23/2024 at 11:30 AM, the Technical Consultant confirmed that the laboratory failed to run QC before patient testing on the day of reference.