

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0483827	(X3) Date Survey Completed 04/16/2019
Name of Provider or Supplier Freestone Medical Center	Street Address, City, State 125 Newman St, Fairfield, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on review of competency assessment documentation and staff interview, the laboratory failed to establish and follow policies and procedures to assess competency for the laboratory technical consultant, clinical consultant, technical supervisor and general supervisor. Findings: 1. Competency assessment materials for consultants and supervisory personnel were requested. None were available or could be offered. The CMS form 209 for the facility lists, separate from the laboratory director, a clinical consultant, two technical supervisors, a technical consultant and two general supervisors. 2. In an interview at the site on 04-16-2019, technical supervisor 2 (CMS form 209) stated she was unaware of the requirement for documented competency assessment for consultants and supervisory personnel. .</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: . Based on review of laboratory procedure for coagulation testing using the ACL Elite</p>

Pro analyzer, laboratory study testing records for 2019 and staff interview, the laboratory failed to follow its own procedure for establishment of a patient normal mean for prothrombin time (PT) prior to introducing Hemosil Recombiplastin lot NO789332. Findings: 1. Laboratory procedure states: Reference Intervals (Patient Normal Range) will be established whenever there is a change in the following: - Instrumentation -Lot numbers of reagents -Sample collection procedures -At least once a year 2. Laboratory procedure further states: Donors will be screened carefully utilizing the following guidelines: 1. Healthy with no known pathological conditions. 2. Not on medication, including oral contraceptives, estrogen therapy drugs, thyroid meds, aspirin or vitamin K. 3. Exclude donors that drink alcohol or have a diet that includes greens. 4. Will span the adult age range. 5. The study will include a fairly even number of males and females. 6. A minimum of 20 donors should be used. (Freestone Medical Center Policy and Procedure, policy number C-005, Patient Normal Range Determination, effective January 1 2017-excerpts) 3. Study materials were reviewed and found to include instrument printouts identified by patient name; some by last and first names, some by last name only, some by specimen ID only. Also included were 25 questionnaires identified by patient name and specimen ID with answer options for: -Age -Sex -Aspirin Y/N -Alcohol Y/N -Oral Contraceptives Y/N -Vitamin K Y/N -Greens in diet Y/N -Thyroid meds Y/N Space for patient signature 4. The questionnaires were found to be in various stages of completion as follows: Filled out and signed, with all disqualifiers marked "N"--5 Filled out and signed, with some disqualifiers marked "Y"--6 Filled out, not signed--4 Not filled out, not signed--9 No questionnaire--1 5. In an interview at the site on 04-16-2019, the laboratory technical consultant (CMS form 209) was unable to verify whether samples from some or all of the patients reviewed were used in the study. .

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
 CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
 Based on review of laboratory personnel competency verification documents for 2017, 2018 and 2019, confirmed by staff interview, laboratory technical supervisor 2 (CMS form 209) failed to evaluate the competency of testing personnel as required. Findings: 1. Laboratory personnel competency verification documents were reviewed. For 2017, verification documentation was found for 4 testing personnel; materials for testing persons 6, 7 and 9 included an 8-page form covering lab duties evaluated using the required methods as applicable, signed by the technical supervisor at that time, who has since left the facility. Also included in this number was general supervisor 2, also listed as a testing person. 2. For 2018, no competency verification documentation was found or could be offered for any laboratory testing personnel. 3. For 2019, forms identical to those used in 2017 were found for testing persons 2, 3, 4 and 6. None of the forms were signed by the laboratory director or technical supervisor, and most bore initials indicating that the testing personnel had been evaluated by each other.

This was confirmed in an interview with technical supervisor 2 at the site on 04-16-2019. 4. No competency verification materials were found or could be offered for the remaining 7 testing personnel listed on CMS form 209.