

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2088100	(X3) Date Survey Completed 05/02/2018
Name of Provider or Supplier Gamma Healthcare Tyler	Street Address, City, State 2211 Roy Road Suite A, Tyler, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: . Based on review of American Proficiency Institute (API) proficiency testing documentation for 2016, 2017 and 2018, confirmed by staff interview, the laboratory director failed to attest to the routine integration of samples into the patient workload using the laboratory's routine methods by signing or designating a qualified individual to sign 7 attestation statements. Findings: 1. API proficiency testing documentation was reviewed. Attestation forms for the following events were signed in the space marked Lab Director (or designee) by the general supervisor (CMS form 209): 2016 Immunology-3rd event 2017 Chemistry-Core-3rd event 2017 Microbiology-3rd event 2017 Hematology/Coagulation-3rd event 2017 Immunology-3rd event 2018 Chemistry-Core-1st event 2. Laboratory policy and procedure documents included a sheet marked Director Designee, which stated the general supervisor was "designated to provide attestation of proficiency testing statements for the Medical Director." The sheet was signed by the laboratory director. 3. Review of the general supervisor's education and training documentation revealed that she was not qualified as a technical consultant for moderate complexity testing or as a technical supervisor for high complexity testing. In an interview at the site on 05-02-2018, the general supervisor stated she was unaware that the delegation of authority to sign attestation statements required the designee to meet those qualifications. .</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p>

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

. Based on review of laboratory policy for hematology testing and patient testing logs for 2017 and 2018, confirmed by staff interview, the laboratory failed to follow its own policy for acceptability of specimens for activated partial thromboplastin time (APTT) coagulation testing. Findings: 1. Laboratory policy states: "Specimens for routine APTT assays on nonheparinized patients uncentrifuged or centrifuged with plasma remaining on top of the cells in an unopened tube kept at 2 to 4 degrees Celsius or 18 to 24 degrees Celsius should be tested within four hours from time of specimen collection." 2. 12 representative patient records from 01-01-2018 to the date of the survey were reviewed. Elapsed time from specimen collection to time of testing ranged from 18 hours, 33 minutes to 3 hours, 32 minutes. Of the 12 representative samples, one (3 hours, 32 minutes) was tested within the allowable time stated in policy. 3. In the time period from 01-01-2017 to 05-02-2018, the laboratory tested 209 specimens for APTT. In an interview at the site, the general supervisor stated that the majority of specimens for APTT assays were tested more than 4 hours after collection.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(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:

. Review of laboratory testing personnel competency verification documentation for 2017 and 2018, confirmed by staff interview, the laboratory director, who serves as technical consultant, failed to verify the competency of 4 of 4 testing personnel. Findings: 1. Laboratory testing personnel competency verification documentation for 2017 and 2018 was reviewed. Forms for all testing personnel were signed by the general supervisor, who also serves a laboratory manager. 2. In an interview at the site on 05-01-2018, the general supervisor confirmed that she had evaluated and signed competency verification forms for all testing personnel. 3. Laboratory policy included an entry titled, "Medical Director: Qualifications, Responsibilities, and Delegations." This entry states in part, "The following responsibilities of the medical director /clinical consultant/technical supervisor are delegated to the Director of Laboratory Services and Laboratory Manager (6) Ensuring competency of current employees through annual evaluations." (Gamma Healthcare Policy and Procedure Gen-15) 4. Review of the general supervisor's education and training documentation revealed that she was not qualified as a technical consultant for moderate complexity testing. In an interview at the site on 05-02-2018, the general supervisor stated she was unaware that the delegation of authority to verify the competency of personnel performing moderate complexity testing required the designee to meet those qualifications. .

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:

. Review of laboratory testing personnel competency verification documentation for 2017 and 2018, confirmed by staff interview, the laboratory director, who serves as technical supervisor, failed to verify the competency of 4 of 4 testing personnel. Findings: 1. Laboratory testing personnel competency verification documentation for 2017 and 2018 was reviewed. Forms for all testing personnel were signed by the general supervisor. 2. In an interview at the site on 05-01-2018, the general supervisor confirmed that she had evaluated and signed competency verification forms for all testing personnel. 3. Laboratory policy included an entry titled, "Medical Director: Qualifications, Responsibilities, and Delegations." This entry states in part, "The following responsibilities of the medical director/clinical consultant/technical supervisor are delegated to the Director of Laboratory Services and Laboratory Manager (6) Ensuring competency of current employees through annual evaluations." (Gamma Healthcare Policy and Procedure Gen-15) 4. Review of the general supervisor's education and training documentation revealed that she was not qualified as a technical supervisor for high complexity testing. In an interview at the site on 05-02-2018, the general supervisor stated she was unaware that the delegation of authority to verify the competency of personnel performing high complexity testing required the designee to meet those qualifications. .