

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0672809	(X3) Date Survey Completed 06/17/2019
Name of Provider or Supplier Sam Houston State University	Street Address, City, State 1608 Avenue J, Huntsville, 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
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: . Based on review of laboratory policy documentation, confirmed by staff interview, the laboratory director (LD) (CMS form 209) failed to specify in writing the duties of the laboratory technical consultant (TC) (CMS form 209). Findings: 1. Review of laboratory policy showed a Delegation of Duties sheet signed by the LD specifying the duties of medical technologists and LD. No mention was made of duties delegated to the TC. No other such documentation was found or could be offered during the survey. 2. In an interview at the site on 06-17-2019, the LD stated that she was unaware of the requirement to specify the duties delegated to the TC in writing. .</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:

Based on review of laboratory competency verification documentation and staff interview, the laboratory technical consultant failed to evaluate the competency of all testing personnel according to the required criteria. Findings: 1. Laboratory personnel competency verification documentation was reviewed. Although the required criteria were listed as options on the provided Personnel Assessment form, methods employed to verify competency were limited to direct observation and review of quality control activities. 2. In an interview at the site on 06-17-2019, the LD stated she was not aware that use of all listed criteria was required to verify personnel competency. It should be noted that the LD meets the regulatory education and training requirements for technical consultant of a moderate complexity laboratory. .