

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0995592	<b>(X3) Date Survey Completed</b> 09/26/2018
<b>Name of Provider or Supplier</b> Paris Cardiology Center	<b>Street Address, City, State</b> 1775 Fm 195, Paris, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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 the laboratory procedure manual and staff interview, the laboratory failed to utilize a written procedure manual for all tests performed by the laboratory. Findings: 1. The laboratory procedure manual was reviewed and found to contain sections on quality management, quality control, proficiency testing, training and personnel responsibilities. No mention was found of testing methods or instrumentation. In an interview at the site on the date of the survey, testing person 1 (CMS form 209) stated that the instrument users' manuals were available to staff as procedure guides. 2. The laboratory procedure manual contained no reference to the specific instruments in use, which included a hematology analyzer added on 09-07-2018. The manufacturers' manuals showed no evidence of review or approval by the laboratory director. .</p>
<b>D6037</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413</p> <p>The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on review of laboratory documentation for 2017 and 2018, surveyor observation and staff interview, the laboratory technical consultant (CMS form 209) was not readily accessible to the laboratory to provide consultation from July 2017 to the time of the survey. Findings: 1. Laboratory documentation reviewed showed no participation by the technical consultant in proficiency testing, personnel competency verification or instrument performance validation from July 2017 to the date of the survey, September 26 2018. 2. In an interview at the site on the date of the survey, testing person 1 (CMS form 209) stated the last date the technical consultant had been on site was in July 2017, and that attempts to contact him via telephone and e-mail in June of 2018 for consultation had gone unanswered. In a subsequent interview on the same date, the clinic supervisor stated that outside consultants had been employed on that one occasion and other options were being considered.