

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0717479	(X3) Date Survey Completed 06/04/2018
Name of Provider or Supplier Gulf Coast Pathologists Llc	Street Address, City, State 2631 McCormick Dr Suite 101, Clearwater, 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
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 competency record review, review of the CMS Laboratory Personnel Report form (CMS 209), and interview with the Cytotechnologist, the laboratory failed to perform annual competency evaluations for 2 out of 3 Testing Personnel (Testing Personnel B and Testing Personnel C and Cytotechnologist C who are the same Testing Personnel) for 2017 and 2018 . Findings included: During record review of the CMS 209, it was found that there were 3 Testing Personnel (Tersting Personnel A, B, and C) listed on the form. During competency record review, it was noticed that Testing Personnel B and Testing Personnel C/Cytotechnologist C did not have annual competency assessments for 2017 and 2018 . During an interview on June 4, 2018 at 12:00 PM, the Cytotechnologist stated that annual competency assessments had not been performed for 2017 and 2018, by the Laboratory Director who is Testing Personnel A and also is the Technical Supervisor, for Testing Personnel B and Testing Personnel C/Cytotechnologist C.</p>
D6107	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting</p>

and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual and interview with the Cytotechnologist, the laboratory failed to have written job descriptions for the Clinical Consultant, Technical Supervisor, General Supervisor, Cytotechnologist General Supervisor, and the Cytotechnologist. Findings included: During review of the laboratory procedure manual, it was found that the manual was missing job descriptions for the Clinical Consultant, Technical Supervisor, General Supervisor, Cytotechnologist General Supervisor, and the Cytotechnologist. During an interview on 06/04/18 at 12:05 PM, the Cytotechnologist confirmed the manual did not contain the job descriptions for the Clinical Consultant, Technical Supervisor, General Supervisor, Cytotechnologist General Supervisor, and the Cytotechnologist