

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2014212	<b>(X3) Date Survey Completed</b>  07/16/2019
<b>Name of Provider or Supplier</b>  Cytodiagnosics Lab	<b>Street Address, City, State</b>  911 Sunset Dr, Hollister, CA	
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>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 observation of cytology slides prepared with Diff-Quik stain, the lack of laboratory document, and interview with the Testing Person/Laboratory Director, it was determined that the laboratory failed to have a written procedure for policy and step-by-step instructions for the Diff-Quik staining process. Findings included: a. Cytology slides randomly selected from March 2016 to July 2019 included the Diff-Quik stain. b. The laboratory was unable to provide for review written policy for use of the Diff-Quik stain and instructions for performing the staining. c. The Testing Person/Laboratory Director affirmed (7/16/19 at 5pm) that Diff-Quik staining was performed on Thyroid FNA (Fine Needle Aspirates); and the failure to have a written policy and procedure of instructions for staff use. d. The reliability and quality of slides prepared using the Diff-Quik stain could not be assured in the absence of a written laboratory policy and procedure. Annual numbers of Thyroid FNAs examined are as follows: Year Annual Volume, Thyroid FNA ----- 2017 51 2018 55 .</p>