Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2030009	05/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Precipio Inc	4 Science Park, New Haven, CT	

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	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to evaluate testing personnel (TP) using the 6 required elements to ensure their competency to perform and report accurate test results. Findings include: 1. Record review on 5/20/19 of the laboratory's personnel competency records for 2017 and 2018 revealed 1 of 5 TP was not evaluated for competency to assess their knowledge and skills to perform and report cytogenetics tests. 2. The laboratory failed to provide documentation for competency assessment of the following personnel: a. Clinical consultant b. Technical supervisor c. General supervisor (GS) 3. Staff interview with the GS on 5/20/19 at 10: 00 AM confirmed the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to follow their established procedure for lot to lot verification in the specialty of pathology. Findings

	include: 1. Record review of the laboratory procedure manual for immunohistochemistry "antibody validation" on 5/20/19 revealed lot to lot validations are to be performed before a new lot of antibodies is placed into use. 2. Record review of the antibody lot to lot validation records on 5/20/19 revealed the following: Antibody Lot# validated Lot # currently in use CD45 Y06092 B02826 CD61 29832 1205105E CD20 16180074 1125903D CD34 5916 1120807A CD3 1614406A 1218010A CD138 21645 1123002P The laboratory failed to provide documentation of lot to lot validation of the above antibodies currently in use. 3. Staff interview with the laboratory supervisor (LS) on 5/20/19 at 1:00 PM confirmed the above findings. The LS further stated lot to lot validation was overlooked due to staffing changes. 4. The laboratory performs 1,000 immunohistochemistry tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and staff interview the flow-cytometry laboratory failed to take corrective action(s) when the laboratory's humidity levels exceeded the acceptable limits. Findings include: 1. Record review on 5/20/19 of the flow-cytometry laboratory's electronic humidity log revealed: a. The acceptable humidity level is 30-80% b. Humidity level documented from 3/28/19 through 5/14/19 revealed humidity level were outside the above acceptable limits on 10 days. c. Corrective action documentation stated "humidity is low. It's okay" 2. Staff interview with the flow-cytometry laboratory supervisor (FLS) on 5/20/19 at 12:30 PM confirmed the above findings. The FLS further stated the humidity is an ongoing issue and the flow cytometry analyzer manufacturer's requirement of humidity level is 30-80%. 3. The laboratory performs 1,000 flow-cytometry tests annually.