Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1076051	03/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Precision For Medicine (Tx)	9240 Kirby Dr Suite 100, Houston, 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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of College of American Pathologists (CAP) attestation statement, the laboratory's proficiency testing records for 2022, and staff interview, it was revealed that the laboratory failed to have documentation of the laboratory director signing two of two attestation statements in 2022. Findings include: 1. A review of CAP's Attestation form revealed the following: "As stated in the February 28, 1992 United States Federal Register under Subpart H 493-801 (b)(1), "the individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient work load using the laboratory's routine methods." The laboratory director or designee and the testing person must sign on the result form." 2. A review of the laboratory's CAP records from 2022 revealed the laboratory failed to have documentation of the laboratory director signing the following 2 attestation statements: - CYH- A 2022 FISH ERBB2 (HER2) Amplification - CYH- B 2022 FISH ERBB2 (HER2) Amplification 3. An interview with the QA manager on 3/22/23 at 9:55 a.m. in the conference room, after review of the records, confirmed the above findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)

	The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory's College of American Pathologists (CAP) proficiency testing records from 2022, and staff interview, it was revealed that the laboratory failed to have documentation of reviewing and evaluating the proficiency testing results for two of two events in 2022. Findings include: 1. A review of the laboratory's CAP proficiency testing records from 2022 revealed the laboratory failed to have documentation of reviewing and evaluating the proficiency testing results for the following 2 events: - CYH - A 2022 FISH ERBB2 (HER2) Amplification - CYH - B 2022 FISH ERBB2 (HER2) Amplification 2. An interview with the QA manager on 3/22/23 at 9:55 a.m. in the conference room, after review of the records, 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 a review of the laboratory's policies, a review of the laboratory's records, and staff interview, it was revealed that the laboratory failed to have documentation of following its policy by ensuring the laboartory director performed an annual review of the laboartory's test report format and the CLIA HER2 NEU FISH Assay Requests and Reporting policy in 2022. Findings include: 1. A review of the laboratory's policy titled 'CLIA HER2 NEU FISH Assay Requests and Reporting' revealed the following: "CLIA Laboratory Director: TASK: - Perform an annual review of this SOP and as a result review the test report format and contents. GENERAL: - Laboratory Director review of the Report format is to be performed during annual review of this SOP." 2. A review of the laboratory's records revealed the laboratory failed to have documentation of the laboratory director performing an annual review of the test report format and the policy review in 2022. 3. An interview with the QA manager on 3/22/23 at 10:20 a.m. in the conferene room, after reveiw of the records, confirmed the above findings.
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 a review of the laboratory's policies, surveyor observation, and staff interview, it was revealed that the laboratory failed to have documentation of monitoring the temperature in the laboratory for twelve of twelve months in 2022. Findings include: 1. A review of the laboratory's policy titled 'CLIA HER2 NEU FISH Procedures' revealed the following: "Slide Pretreatment: - Remove the Pre-Treatment Solution from the water bath and remove the lid to allow the slides to cool for 15 mins. at room temperature. - Transfer the slides to a jar with diluted was buffer for 3 minutes at room temperature (20 - 25 C)." 2. Surveyor observation of the laboratory on 3/22/23 at 11:20 a.m. revealed the laboratory failed to have a mechanism in place to monitor the room temperature in the laboratory. 3. The QA manager was asked to provide documentation of monitoring the room temperature of the laboratory for all 12 months in 2022, no documentation was provided. 4. An interview with the QA manager on 3/22/23 at 11:30 a.m. in the conference room, after review of the records, confirmed the above findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel files, and staff interview, it was revealed that the technical supervisor failed to perform a competency assessment on three of three testing personnel performing high complexity testing in 2022. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified three testing personnel performing high complexity testing. 2. A review of the laboratory's personnel records revealed that there was no documentation of the technical supervisor performing a competency assessment on testing person #1, testing person #2, and testing person #3 in 2022. 3. An interview with the QA manager on 3/22/23 at 10:40 a.m. in the conference room, after review of the records, confirmed the above findings.