Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1076051	04/07/2021
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 representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
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 review of the laboratory records from 2019 to 2021, laboratory policies, and confirmed in interview, the laboratory failed to assess competency for 1 of 2 technical supervisors. Findings were: 1. Review of the laboratory policy Employee Training QA02, Version 06 effective 7/29/19 under CLIA Competency and Performance Reviews revealed "competency reviews are performed by qualified staff (e.g. laboratory director or technical supervisor) approximately 6 months (+/- 1 month) after hire and annually (+/- 1 month) thereafter for all employees performing CLIA non-waived (medium or high complexity) testing, including technical supervisor. 2. A review of the laboratory records from 2019 to 2021 revealed 1 of 2 technical supervisors (TS #2) did not have documentation of a competency assessment. 3. An interview with the Quality Assessment Specialist on 4/7/21 at 1035 hours in the conference room confirmed the above findings.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)

	The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing records from 2019 to 2021, laboratory test records, and confirmed in interview, the laboratory failed to verify the accuracy of 1 of 1 test (FISH HER2 amplification) not graded by the proficiency testing program for 2 of 4 events reviewed. Findings were: 1. Review of the CAP exception reason codes (Rev 8/2019) revealed the "the laboratory must identify all of the analytes with an exception reason code, review, and document the acceptability of performance as outlined below and retain documentation of review for at least 2 years. The actions laboratories should take include but are not limited to: 26 - education challenge; review participant summary for comparative results and document performance accordingly. Evaluation criteria are not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation. response to CAP is not required. 27 - lack of participant or referee consensus; document that the laboratory performed a self-evaluation and compared its results to the intended response when provided in the participant summary. If comparison is not available, perform and document alternative assessment (ie, split samples) for the period that commercial PT reached non-consensus to the same level and extent that would have been tested." 2. Review of the CAP proficiency testing records from 2019 to 2020 revealed 2 of 4 events when the laboratory failed to document the self-evaluation per CAP. CYH-A 2020 FISH HER2 Amplification Specimen CYH-02 [27] CYH-B 2019 FISH HER2 Amplification Specimen CYH-99D [26] Specimen CYH-99E [26] Specimen CYH-99F [26] 3. An interview with the Quality Assessment Specialist on 4/7/21 at 1010 hours in the conference room 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 review of the manufacturer's instructions, laboratory and patient records from January, March and August 2020, and confirmed in interview, the laboratory failed to store the HER2 IQFISH pharmDx reagents per the manufacturer recommended storage temperature for 2 of 10 days reviewed: Findings were: 1. Review of the Dako HER2 IQFISH pharmDx package insert (PD04091US_01 /K573111-5) under Storage revealed "store the HER2/CN-17 IQISH Probe mix (vial

	3) at -18 C. All other reagents can be stored at 2-8 C in the dark." 2. Review of the laboratory procedure Temperature and Humidity Monitoring (SOP LM02, Rev 4) under Controlled Temperature Units revealed: "Freezer: -30 to -10 C (Deep Freeze -90 to -70); Refrigerator: 2 - 8 C" 3. Random review of laboratory freezer and fridge temperature logs from January, March and August 2020 revealed 2 of 10 days when the temperature was outside of the acceptable limits of 2-8 C for the fridge and -18 C for the freezer. 8/20/20: Refrigerator 1.5 C; Freezer -15 C 1/29/20: Refrigerator low of 1.3 C; high of 6.1 C; Freezer high of -13.4, low of -25.1 C 4. Review of the above dates revealed the laboratory performed FISH HER2 amplification patient testing. 8/20/20: specimen ID 69867 1/29/20: specimen ID 68759 5. An interview with the Quality Assessment Specialist on 4/7/21 at 1540 hours in the conference room confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory and patient test records from 2019 to 2021, CMS116, and confirmed in interview, the laboratory failed to document complete verification studies for 1 of 1 test (FISH HER2 amplification) before patient testing. Findings were: 1. Review of the laboratory records from 2019 to 2021 revealed the laboratory started FISH HER 2 amplification patient testing on 02/2019. 2. Review of the laboratory policies revealed no documentation of a policy for verification of an unmodified FDA-cleared test system. 3. Review of the laboratory records from 2019 to 2021 revealed no documentation of the verification of the FISH HER2 amplification test using the Dako HER2 IQFISH pharmDx assay. 4. Review of the CMS116 signed by the laboratory director on 4/7/21 revealed the laboratory performed 10 tests annually. 5. An interview with the quality assessment specialist on 4/7/21 at 1310 hours in the conference room confirmed the above findings. He was unaware that a verification study was required with an FDA approved test.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, review of laboratory and quality control records from 2019-2021, CMS116, and confirmed in interview, the laboratory failed to establish and document performance specifications for their research use only QC (quality control) material for 1 of 1 test: FISH HER2 amplification. Findings

	included: 1. Review of the laboratory quality control records from 2019-2021 revealed the laboratory used StatLab TruQ TMA 2-score quality control slides for 1 of 1 test: FISH HER2 amplification assay. 2. Review of the product data sheet for the StatLab TruQ TMA 2-score under intended use revealed "research use only (validation purposes)." 3. Review of the laboratory records available revealed no documentation of the establishment of performance specification for the above control. 4. Review of the CMS116 signed by the laboratory director on 4/7/21 revealed the laboratory performed 10 tests annually. 5. An interview with the quality assessment Specialist on 4/7/21 at 1310 hours in the conference room confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory quality assessment plan, review of manufacturer's instructions, review of the laboratory's environmental monitoring records, and review of quality control records, it was revealed the laboratory's quality assessment policies failed to monitor, assess and correct problems in analytic systems. The findings were: 1. The laboratory failed to store the HER2 IQFISH pharmDx reagents per the manufacturer recommended storage temperature. Refer to D5413 2. The laboratory failed to document complete verification studies for 1 of 1 test (FISH HER2 amplification) before patient testing. Refer to D5421 3. The laboratory failed to establish and document performance specifications for their research use only QC (quality control) material for 1 of 1 test: FISH HER2 amplification. Refer to D5425
D6127	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the CMS209, laboratory policy, laboratory personnel records for 2019 to 2021 and confirmed in interview, the technical supervisor failed to perform the initial and semiannual competency for 4 of 4 testing persons (TP) for 1 of 1 high complex testing for FISH HER2 amplification testing. Findings were: 1. Review of the CMS209 signed by the laboratory director on 4/7/21 revealed 4 testing persons. 2. Review of the laboratory policy Employee Training QA02, Version 06 effective 7/29 /19 under CLIA Competency and Performance Reviews revealed "competency reviews are performed by qualified staff (e.g. laboratory director or technical supervisor) approximately 6 months (+/- 1 month) after hire and annually (+/- 1 month) thereafter for all employees performing CLIA non-waived (medium or high complexity) testing, including technical supervisor. 3. Review of the personnel records from 2019-2021 revealed no initial and semiannual competency for 4 of 4 testing persons (TP1-hire date 04/2010, TP2- hire date 06/2017, TP3-hire date 08

	/2019, TP4-hire date 05/2019). 4. An interview with the quality assessment specialist on 4/7/21 at 1035 hours in the conference room confirmed the above findings.