Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2206463	(X3) Date Survey Completed 12/06/2022
Name of Provider or Supplier Precious Health Of Lakewood	**Street Address, City, State** 886 River Avenue, Lakewood, NJ	

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
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: a) Based on surveyor review of the Procedure Manual (PM), Calibration Verification (CV) records and interview with the Techincal Consultant (TC), the laboratory failed to have a procedure for CV at the time of survey. The TC confirmed on 12/6/22 at 11: 40 am the laboratory did not have a procedure for CV. b) Based on surveyor review of the PM, Test Reports (TR) and interview with the TC, the laboratory failed to have a procedure for Parameter Data Flags at the time of survey. The TC confirmed on 12/6 /22 at 11:30 pm that the laboratory did not have the aforementioned procedure.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of patient work records, review of the Manufacture Operator Manual (OM) and interview with the Techincal Consultant (TC), the laboratory failed to follow the OM for Hematology testing performed on the Cell-Dyn

	Emerald from August 2020 to the date of survey. The findings include: 1. The OM stated patient results with S flags ""Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required." 2. 4 out of 7 patient work records had "S" flags. But the laboratory did not follow the OM. 3. The TC confirmed on 12/6/22 at 11:40 am the laboratory failed to follow the OM.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of Calibration Verification (CV) records, Operators Manual (OM) and interview with the Technical Consultant (TC), the laboratory failed to follow the manufacturer's test systems instructions for performing and documenting Calibration at least once every six months for Hematology Tests performed on the Abbott Cell Dyn analyzer in the calendar year 2022. The findings include: 1. The the manufacturer's test systems instructions stated prior to calibration: "Verify instrument precision by running a fresh, normal whole blood specimen ten times into the PRECISION file. Refer to Section 9: Service and Maintenance, Subsection: Precision for information on using QC files. Ensure that CV% results are within the limits as provided in Section 4: Performance Characteristics and Specifications. Record the results below or attach a printout to this document". 2. A review of CV records revealed that the laboratory did not perform "Precision Check" as required prior to CV. 3. The TC confirmed on 12/6/22 at 11:30 am that the laboratory failed to follow the manufacturer's test systems instructions as stated above.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, Bacitracin discs in use and interview with the Testing Personnel (TP), the laboratory failed to check each lot

	number and shipment of Bacitracin Discs for positive and negative reactivity from 11 /1/22 to the date of the survey. The finding includes: 1. There was no record of Bacitracin QC for Lot # 2025098 currently in use. 2. Approximately 15 patient run and reported each day. 3. The TC confirmed on 12/6/22 at 10:50 am that the laboratory did not perform QC on Bacitracin disc as stated above.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Technical Consultant (TC), the laboratory failed to check each batch of Selective Strep Agar (SSA) used for Throat Culture (TC) tests for sterility, its ability to support growth and select or inhibit specific organisms and document the physical characteristics of the media no the date of the survey. The findings include: 1. There was no documented evidence the above mentioned QC was performed on SSA lot # 148391. 2. The TC confirmed on 12/6/22 at 12:00 pm that the laboratory did not perform QC as stated above.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on the surveyor review of the Final Report (FR) and interview with the Techincal Consultant (TC), the laboratory failed to have a Reference Range (RR) for Strep A Throat Culture-Overnight w/BBL disk results from August 2020 to the date of the survey. The TC confirmed on 12/6/22 at 12:15 pm that the above test did not have a RR on the FR.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure that PS procedures performed for Complete Blood Count tests performed on the Abbott cell dyn emerald analyzer were adequate from 8/28/22 to the date of survey. The findings include: 1. There was no evidence that linearity was performed. 3. There was no evidence that a Reference Range was verified. 4. The TC confirmed on 12/6/22 at 11:15 am that PS records were not adequate.