Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0860676	10/15/2020
Name of Provider or Supplier	**Street Address, City, State**	
Gastro Health Llc	9970 Central Park Blvd Ste 101, Boca Raton, FL	

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	A recertification survey conducted on 10/15/2020 found that Boca Raton Gastroenterology Associates LLC clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. 1- Cited the following Conditions: -D5200 General Laboratory Systems -D5400 Analytic Systems -D6000 Moderate Complexity Laboratory Director -D6063 Laboratory Testing Personnel 2- The following Standards deficiencies are repeat cites from the previous recertification survey on 9/18/2018: -D2015 Testing of Proficiency Testing Samples -D2128 Hematology -D5209 Personnel Competency Assesment Policies -D5439 Calibration and Calibration Verification
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory did not maintain all the proficiency testing (PT) records and did not have the required signatures on all the documentation for the period reviewed (2019-2020). Findings Include: A review of the American Proficiency Institute (API) records for the Hematology specialty for the past 2 years revealed that: -The laboratory failed to have attestation signed by testing

	personnel (TP) for 2nd event of 2019. -There was no copy of attestation for 2nd event of 2020. -The Laboratory Director or its designee failed to sign API PT performance review evaluation for 5 out of 5 events reviewed 2019 (1, 2 and 3) 2020 (1 and 2). During an interview on 10/15/2020 at 11:30 AM, TP A confirmed that the forms listed above were not signed as described.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) record by American Proficiency Institute (API) and staff interview, the laboratory failed to score at least 80 % on the following analytes: Red Blood Cell (RBC) and White Blood Cells Differential (WBC) analyte in 1 out of 5 events reviewed for Hematology specialty. Findings include: Review of PT records revealed a score of 60 % for RBC in the 1st event of 2019 and for WBC a score of 67 % in the 3rd event of 2019. During an interview on 10/15/2020 at 12:30 PM, testing personnel (TP) A, confirmed the proficiency testing failure.
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) and staff interview, the laboratory received an unsatisfactory score for 1 (3rd event 2019) out of 5 events for Hematology reviewed (2019-2020). Findings include: Review of API PT records revealed a score of 67 % for White Blood Cells Differential (WBC) in the 3rd event of 2019 resulting in a failing score of 71 % for the Hematology specialty. During an interview on 10/15/2020 at 12:30 PM, the testing personnel (TP) A confirmed the proficiency testing failure.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document remedial action for unsatisfactory proficiency testing (PT) results for 1 out of 5 events

	of Hematology specialty and for 2 out of 2 Hematology analyte unsatisfactory scores in 2019, Red Blood Cells (RBC) 1st event and White Blood Cells Differential (WBC) 3rd event of 2019. Findings include: -Review of American Proficiency Institute (API) proficiency testing results in 2019 and 2020, showed that the laboratory had unsatisfactory score of 71 % for the 3rd Event of Hematology of 2019 due to an unsatisfactory score on WBC of 67 % and had an analyte unsatisfactory score for RBC of 60 % for the 1st event of 2019. -No documentation of the review and corrective actions were provided by the laboratory. -The laboratory failed to follow the Plan of Correction submitted on 10/10/2018. During an interview on 10/15/2020 at 2:30 PM, the office manager confirmed that the laboratory had no documentation of the remedial actions to correct the PT failing results.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory failed to document the competency assessment of testing personnel (TP). Laboratory failed to follow their Quality Assurance (QA) policy for the period of 2019 and 2020. See D5209 and D5293
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 document the annual employee competency testing, for 3 out of 3 testing personnel (TP) (A, B and C) during the 2 years reviewed. Findings include: -Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 08/12/2020 revealed that there were 3 TP (A, B and C). -Record review revealed that the laboratory failed to document the laboratory competency evaluation of 3 out of 3 TP for 2019 and 2020 as per Clinical Laboratory Improvement Amendments (CLIA) guidelines. During an interview on 10/15/2020 with Office Manager at 2:30 PM, she confirmed that the laboratory failed to document the competency for 3 TP as required by CLIA guidelines.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the

	effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow their Quality Assurance (QA) policy for 2 out of 2 years (2019 and 2020). Findings include: -Review of QA policy showed that the laboratory director (LD), monitor and evaluates all QA activity. -The laboratory had a QA checklist for monthly QA evaluation. Review of the QA checklist records for 2019 and 2020 during the survey revealed that the LD failed to sign the QA Monthly checklists. -All monthly QA checklist reviewed for 2019 and 2020 stated that the laboratory fulfilled the requirements for: a) Quality Control (QC) for Controls/calibrations performed. The laboratory had no documentation of the calibrations performed on the Cell Dyne Emerald analyzer during 2019 and 2020. The QA failed to identify that the laboratory failed to perform the Cell Dyne Emerald analyzer calibrations for 2 out of 2 years. No corrective actions documented for this failure. See 5439. b) Proficiency Testing (PT), PT results were reviewed, and failures investigated, and remedial actions documented. The laboratory had no documentation of PT results review (See D 2015 and D2128). c) Personnel Policies, no competency assessment of Testing Personnel documented (See D 5209). During an interview on 10/15/2020 at 2:30 PM, with the Office Manager, she confirmed that records listed above did not have the LD signature and that the QA process failed to solve the failures listed above.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform calibration on the Cel Dyn Emerald hematology analyzer for 2019 and 2020. See D5439
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test

	system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have documentation of the calibration of the Cell Dyn Emerald hematology analyzer. Findings include: -Review of procedure manual revealed that the laboratory will perform calibration Cell Dyn Emerald at least every 6 months. -Review of the Cell Dyn Emerald workbooks showed that there were no records of calibration performed since 10/2018 until 10/2020. -The laboratory tested 461 patients from 1/1/2019 to 10 /15/2020. During an interview on 10/15/2020 at 2:30 p.m., the office manager confirmed that there were no records of calibration for the Cell Dyn Emerald analyzer in the last 2 years.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to provide overall management and direction. See D6013, D6019, D6021 and D6030.
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 record review and staff interview the Laboratory Director (LD) failed to ensure that the laboratory performed calibration of the Cell Dyne Emerald hematology analyzer at least every 6 months for 2019 and 2020. See D5439

D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) did not complete and document a plan of corrective action when a proficiency testing result was unsatisfactory. See D2128
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and staff interview the Laboratory Director (LD) failed to ensure that the laboratory followed the Quality Assurance policy. See D5293
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to perform competency assessment on 3 out of 3 testing personnel (A, B and C) for 2019 and 2020. See D5209
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421

	The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review and interview with Office Manager, the laboratory failed to verify the education of 2 (B and C) out of 3 (A-C) Testing Personnel. See D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the education in 2 (B and C) out of 3 (A-C) testing personnel (TP). Findings include: -Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director on 08/12/2020 revealed that there were 3 TP (TP A-C). -Review of employee files revealed that there was no diploma on file for TP B and C During an interview on 10/15/2020 at 2:30 PM with office manager, she confirmed that the laboratory failed to have documentation of proof of the education requirement for the TP(s) of reference.