Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0860676	09/18/2018
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
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 two years (2016 -2018) record review of API (American Proficiency Institute) hematology proficiency testing results and interview with office manager, the laboratory failed to retain documents showing the completion of proficiency testing for two of six events. The findings include: On September 18, 2018 at 2:00pm API proficiency testing results record review (September 2016 - Sept, 2018) showed no documentation of the testing performed for 2nd event 2017 and 1st event, 2018. During an interview on September 18, 2018, at 3:15pm, the office manager confirmed that the laboratory did not retain documents showing the completion of proficiency testing performed for 2nd event 2017 and 1st event, 2018.
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a

	score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on two years (2016 -2018) record review of API (American Proficiency Institute) Hematology proficiency testing results and interview with office manager, the laboratory failed to submit the proficiency testing results in the specified timeframe for the 1st Hematology event in 2018 resulting in a score of 0% for hematology analytes. The findings include: On September 18, 2018 at 2:00pm API proficiency testing results record review (September 2016 - Sept, 2018) showed 0% score for Hematology, Cell I D or WBC Diff (cell identification or white blood cell differentiation), RBC (red blood cell), HCT (hematocrit), HGB (hemoglobin), WBC (white blood cell), and Platelets for 1st event, 2018. During an interview on September 18, 2018, at 3:15pm, the office manager confirmed that the laboratory submitted the test results after the required date for hematology 1st event 2018.
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 two years record review (year 2016 -2018) and interview with office manager, the laboratory failed to review and to take and document remedial action for 1st event, 2018 API (American Proficiency Institute) unsatisfactory proficiency testing results for 6 out of 6 hematology analytes. The findings include: On September 18, 2018 at 2:00pm API proficiency testing results record review (September 2016 - Sept, 2018) showed that laboratory had unsatisfactory score of "0" for Cell I D or WBC Diff (cell identification or white blood cell differentiation), RBC (red blood cell), HCT (hematocrit), HGB (hemoglobin), WBC (white blood cell), and Platelets for 1st event, 2018. API performance evaluation 2018 Hematology/Coagulation -1st event form showed that laboratory did not review the performance summery, and did not take corrective action for the failed event. During an interview on September 18, 2018, at 3:15pm, the office manager confirmed that: 1- Laboratory had unsatisfactory score of 0% for Cell I D or WBC Diff (cell identification or white blood cell differentiation), RBC (red blood cell), HCT (hematocrit), HGB (hemoglobin), WBC (white blood cell), and Platelets for 1st event, 2018- API proficiency testing results. 2- Laboratory did not review the performance summery, and did not take corrective action for the failed - API performance 2018 Hematology/Coagulation -1st event.
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 interview with office manager, hematology specialty laboratory failed to establish and follow written policies and procedures to access testing personnel competency for Cell-Dyn 1700 hematology analyzer for the two year record review period (9/2016 - 9/18/18). The findings include: 1- Laboratory Procedures and policy records reviewed on 9/18/18 at 2:30pm for two-year review period (9/2016 - 9/18/2018) did not show established policy to access testing personnel competency on Cell-Dyn 1700 hematology analyzer. 2- Annual and semiannual 'Associate personnel performance appraisal' for three out of three testing personnel for two year record review period (9/2016 - 9/18/2018) did not include all the 'CLIA competency assessment' criteria for testing personnel. During an interview on September 18, 2018, at 3:15pm, the office manager confirmed that: a- the laboratory did not establish policy to access testing personnel competency for Cell-Dyn 1700 hematology analyzer. b- Annual and semiannual 'Associate personnel performance appraisal' for three out of three testing personnel for two year record review period (9/2016 - 9/18/2018) did not include all the 'CLIA competency assessment' criteria for for testing personnel.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on observation, record review for two-year period (2016 to 2018) and interview with laboratory manager, the laboratory failed to follow procedure manual for: - testing the proficiency testing. - Instrument calibration. - Instrument maintenance. - Annual assessment of the laboratory QA plan. - Personnel assessment policy. -Quality assurance plan. The findings include: Procedure manual review on September 18, 2018 at 1:30PM stated that; 1- 100% of all PT (proficiency testing) will be acceptable as determined by CLIA and PT provider's acceptable criteria. 2- All PT (proficiency testing) results will be reviewed by the laboratory manager. Corrective action will be taken for all unacceptable results. All PT results will be reviewed by the laboratory director. 3- 100% of all calibration verification will be performed and documented. Action for unacceptable results will be reviewed and be resolved immediately. 4- Calibration of Cell-Dyn 1700- the calibration should be performed every six months minimum. Ideally, they should be run every time receive a new batch of controls. Also, they should be checked when controls are not running correctly and all other avenues have been exhausted. It should also be checked after any repairs have been done to the machine. 5- 100% of all required maintenance will be performed and documented. 6- The effectiveness of any action will be assessed and documented. If further actions are necessary to solve a problem, they will be taken and their effectiveness be assessed. An annual assessment of the effectiveness of the laboratory's QA (quality assessment) plan will be made. 7- Findings and conclusions of monitoring and evaluation, including actions taken to solve problems and improve care, will be documented and reported to laboratory personnel as indicated. 8- Personnel assessment policy failed to establish and follow written policies and procedures to access testing personnel competency for Cell-Dyn 1700 hematology analyzer. 9- Actions taken to resolve problems- when results of evaluation procedures

	and monitors point to an area of concern, a specific problem, or an opportunity for improvement of patient care, action will be taken as soon as possible by the laboratory manager or director. 10- Communication of information- Findings and conclusions of monitoring and evaluation, including actions taken to solve problems and improve care, will be documented and reported to laboratory personnel as indicated. 11- Installation procedures and special requirements-maximum relative humidity 80% for temperatures up to 90*F(32*C). Two years (2016 -2018) records review at 2PM on 9 /18/18 showed that laboratory did not follow procedure manual for: A) Instrument calibration- D5439. B) Patient test report- D5787. C) Humidity monitoring- D5413. D) Preventive maintenance-D 5429. E) Proficiency testing- D2015, D2127, D2128, D6091, D6092. F) Annual and semiannual testing personnel assessment- CLIA competency assessment criteria for testing personnel for hematology analyzer- D5209. G) The laboratory's monthly quality assurance checklist for two years (2016 - 2018), did not indicate if there had been any identified issues. The checklist was checked off 'yes' for following all the policies. H) No other quality assessment records other than the monthly quality assurance checklist. I) No records of remedial actions taken assessment of action- documentation of improvement, communication of information During an interview on September 18, 2018, at 3:15pm, the office manager confirmed the findings A to I and confirmed that the laboratory did not follow the procedure manual (1 to 11).
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 observation, record review and the interview with the office manager, the laboratory failed to monitor and record the daily humidity from 9/2016 to 9/18/2018 (for two-year review period) for hematology specialty. The findings include: 1) On 9 /18/18 at 1:30pm, surveyor did not see the records for daily humidity check in instrument maintenance and temperature record logs. 2) Cell Dyn hematology analyzer operator's manual stated installation environment as 'maximum relative humidity 80% for temperatures up to 90*F (32*C). 3) During a laboratory tour at 2:30 PM, surveyor did not observe humidity monitoring device. During an interview on September 18, 2018, at 3:15pm, the office manager confirmed that the laboratory did not have the humidity-monitoring device and did not monitor the humidity as part of the environmental requirement for Cell Dyn hematology analyzer.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on observation, record review and interview with office manager, laboratory failed to have: 1-Preventive maintenance for Quest Diagnostics and LabCorp horizon centrifuges after 8/13/2015. 2- The manufacturer's instructions -operator's manual for the recommended maintenance and function checks for Quest Diagnostics and LabCorp horizon centrifuges. The findings include: During a laboratory tour on 9/18 /18 at 2:30 pm, surveyor observed two centrifuges; Quest Diagnostics Horizon model 642 E and LabCorp horizon with inspection sticker dates on centrifuges as 08/13 /2015, due date 08/2016. There was no manufacturer's instructions or operator's manual for the recommended maintenance and function checks for the centrifuges. There were no other maintenance records for the two centrifuges. During an interview on September 18, 2018, at 3:15pm, the office manager confirmed that the laboratory did not perform maintenance on centrifuges after 8/13/15 and laboratory did not have manufacturer's instructions or operator's manual for the recommended maintenance and function checks for Quest Diagnostics Horizon model 642 E and LabCorp horizon centrifuges.
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 instrument calibration record review for two-year period (9/2016 to 9/18 /2018) and interview with the office manager, the laboratory failed to conduct and document the calibration for at least every six months for Cell Dyn Emerald hematology analyzer. The findings include: Calibration record review on 9/18/18 at 2: 00pm from two-year review period (8/2016-9/18/2018) showed that the laboratory did not perform the calibration for Cell Dyn Emerald hematology analyzer after January 2017 to May 2018, and did not have the calibration records for that. During an interview on 9/18/18 at 3:15 PM, office manager confirmed that the laboratory did not perform the calibration for Cell Dyn Emerald hematology analyzer after January 2017 to May 2018 and did not have the calibration records after January 2017 to May 2018.

D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on two patient test record review of hematology test results and interview with office manager, the laboratory failed to have the testing person's identity, patient's ID number and review signature in the computer scanned test results. The findings include: On September 18, 2018 at 2:45pm, surveyor reviewed two hematology test results, #1 and #2. - Patient # 1 had no sample ID or operator ID . - Patient # 2 had no operator ID and the hand written date was changed to match the instrument printout date. -No physician's signature for reviewed results. During an interview on September 18, 2018, at 3:15pm, the office manager confirmed that: -Patient # 1 had no sample ID number or operator ID number. - Patient # 2 had no operator ID number and the hand written date was changed on scanned copy. -there was no physician's signature for reviewed results.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on two years (2016 -2018) record review of API (American Proficiency Institute) hematology proficiency testing performance evaluation report and interview with office manager, the laboratory director failed to review and identify problems that required corrective action for the proficiency testing reports received for five of five events. The findings include: On September 18, 2018 at 2:00pm API proficiency testing results record review (September 2016 - Sept, 2018) showed proficiency testing performance evaluation reports blank for performance review and corrective action for 3rd event 2016, three events of 2017 and 1st event of 2018. During an interview on September 18, 2018, at 3:15pm, the office manager confirmed that the laboratory director did not review the API hematology proficiency testing performance evaluation report form for 3rd event 2016, three events of 2017 and 1st event of 2018.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

	This STANDARD is not met as evidenced by: Based on two years (2016 -2018) record review of API (American Proficiency Institute) hematology proficiency testing (PT) results and interview with office manager, the laboratory director failed to ensure that an approved corrective action plan was followed for unsatisfactory performance, 1st event-2018. The findings include: On September 18, 2018 at 2:00pm API proficiency testing results record review (September 2016 - September 2018) showed performance summery 2018 hematology/Coagulation -1st event, score 0%, hematology analytes with notes as 'failure to participate'. Proficiency testing performance evaluation report- blank for performance review and corrective action, 1st event 2018. There was no records to show any approved corrective action plan or corrective action for the 0% score for hematology 1st event, 2018. During an interview on September 18, 2018, at 3:15pm, the office manager confirmed that the laboratory director did not review proficiency testing performance evaluation report and there was no other records to show any approved corrective action plan or corrective action for the 0% score for hematology 1st event, 2018.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on observation, record review for two-year period (2016 to 2018) and interview with laboratory manager, the laboratory director failed to ensure that all necessary and appropriate remedial actions were taken by staff and that staff recorded the performance of the remedial actions. The findings include: Based on two years (2016 -2018) record review at 2PM on 9/18/18 showed A) No instrument calibration- D5439. B) Patient test report record with no operator ID, no sample ID and hand written date was changed to match the instrument printout date, no review signature- D5787. C) No humidity monitoring - requirement for the hematology analyzer- D5413. D) No preventive maintenance for Quest Diagnostics and LabCorp horizon centrifuges -D5429. D) Proficiency testing- D2015, D2127, D2128, D6091, D6092. E) Annual and semiannual 'Associate personnel performance appraisal' did not include the 'CLIA competency assessment' criteria for testing personnel for hematology analyzer- D5209. F) That the laboratory's 'monthly quality assurance checklist' for two years (2016 - 2018), did not indicate if there had been any identified issues. The checklist was checked off 'yes' for following all the policies. G) That laboratory director did not review and sign the 'monthly quality assurance checklist'. H) That there was no other quality assessment records other than the monthly quality assurance checklist. I) No records to show if necessary and appropriate remedial actions were taken by staff and that staff recorded the performance of the remedial actions. During an interview on September 18, 2018, at 3:15pm, the office manager confirmed the findings A to I.