| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 14D2153245 | 04/10/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Comprehensive Gastrointestinal Health | 40 Skokie Blvd, Northbrook, IL | |

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 |
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| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the federal Casper Report 0096D, laboratory policies and procedures, lack of laboratory proficiency testing (PT) records, and interview with the laboratory representative; the laboratory failed to enroll in proficiency testing challenges from the start of testing, 11/11/2021, to the date of survey, 04/10/2024, for testing performed on the BioFire FilmArray Gastrointestinal (GI) Panel in the specialties of bacteriology and virology. Findings include: 1. Review of the laboratory's policy and procedure manual found the policy, "Quality Assessment Plan", which indicated, under "Proficiency Testing", "This laboratory will enroll in formal proficiency testing appropriate to the test menu...." 2. A lack of PT records revealed that the laboratory failed to enroll in testing for the following regulated bacteriology organisms: a) C. difficile b) Campylobacter c) Escherichia coli (toxigenic) d) Plesiomonas e) Salmonella f) Shigella g) Vibrio h) Yersinia 3. A lack of PT records revealed that the laboratory failed to enroll in testing for the following regulated virology organisms: a) Adenovirus b) Astrovirus c) Norovirus d) Rotavirus e) Sapovirus 4. Review of the federal Casper report 0096D revealed no scores were reported to the Center for Medicare and Medicaid Services from the start of testing, 11 /11/2021, to the date of survey, 04/10/2024, for the specialties of bacteriology and |

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| | virology. 5. Review of six of six patient test results confirmed the laboratory was reporting results for the above-mentioned regulated organisms. a) P01, Test Date: 09 /14/2022 b) P02, Test Date: 12/09/2022 c) P03, Test Date: 04/19/2023 d) P04, Test Date: 07/10/2023 e) P05, Test Date: 11/27/2023 f) P06, Test Date: 03/18/2024 6. During the survey on 04/10/2024 at 08:55 am, the laboratory representative confirmed the above findings. |
| **D5200** | GENERAL LABORATORY SYSTEMS<br>CFR(s): 493.1230<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the laboratory records, a lack of documentation, and interview with the laboratory representative; the laboratory failed to properly manage and evaluate the overall quality of testing by failing to perform bi-annual evaluation for testing performed on the BioFire FilmArray Gastrointestinal (GI) Panel in the subspecialty of parasitology. See D5217. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policy and procedure manual, lack of bi-annual method accuracy (proficiency testing) documentation, and interview with the laboratory representative; the laboratory failed to perform bi-annual method accuracy from the start of testing, 11/11/2021, to the date of survey, 04/10/2024, for testing performed on the BioFire FilmArray Gastrointestinal (GI) Panel in the subspecialty of parasitology. Findings include: 1. Review of the laboratory's policy and procedure manual found the policy, "Quality Assessment Plan", which indicated, under "Proficiency Testing", "This laboratory will enroll in formal proficiency testing appropriate to the test menu...." 2. A lack of documentation revealed no data for the bi-annual method accuracies for the following parasitology organisms: a) Cryptosporidium b) Cyclospora c) Entamoeba histolytica d) Giardia 3. Review of six of six patient test results confirmed the laboratory was reporting results for the above-mentioned organisms. a) P01, Test Date: 09/14/2022 b) P02, Test Date: 12/09/2022 c) P03, Test Date: 04/19/2023 d) P04, Test Date: 07/10/2023 e) P05, Test Date: 11/27 /2023 f) P06, Test Date: 03/18/2024 4. Interview with the laboratory representative on 04/10/2024, at 08:55 am, confirmed the above findings. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g) |

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| | Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of patient test results, laboratory quality control (QC) records, laboratory policies and procedures, manufacturer's product insert, and interview with the laboratory representative; the laboratory failed to ensure negative and positive control materials were tested each day of testing in the sub-specialties of bacteriology, virology, and parasitology prior to reporting patient test results. Findings include: 1. Review of the laboratory's policy and procedure manual found the policy, "Quality Assessment Plan", which indicated, under "Quality Control", "For each test system used, we will follow the manufacturer's instructions or the [Clinical Laboratory Improvement Amendments] CLIA regulations, whichever is stricter, to ensure accuracy and precision for our test results." 2. Review of the laboratory's policy and procedure manual found the procedure, "BioFire FilmArray Gastrointestinal (GI) Panel Testing Procedure", which indicated, under "Quality Control", "No external control run is needed on a daily basis." 3. Review of the BioFire FilmArray Gastrointestinal (GI) Panel manufacturer's product insert, under "External Controls", indicated "External controls should be used in accordance with laboratory protocols and the appropriate accrediting organization requirements, as applicable." 4. Review of six of six patient test results confirmed the laboratory had not run QC on the date patient testing was performed. Patient: Date of Test: Date QC Performed: P01 09/14 /2022 04/18/2022 P02 12/09/2022 09/30/2022 P03 04/19/2023 09/30/2022 P04 07/10 /2023 09/30/2022 P05 11/27/2023 07/12/2023 P06 03/18/2024 11/28/2023 5. During the survey on 04/10/2024 at 10:21 am, the laboratory representative revealed that QC was only being performed upon a new lot number and/or shipment of BioFire FilmArray Gastrointestinal (GI) Panel testing pouches. |