Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 15D2256543	**(X3) Date Survey Completed** 09/12/2024
Name of Provider or Supplier Baptist Health Floyd At Jefferson Ridge	**Street Address, City, State** 3516 E 10th St, Jeffersonville, IN	
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 proficiency testing desk review survey was completed on 9/12/2024. It was determined that the following condition-level deficiencies existed: 42 Code of Federal Regulation (CFR) 493.803(a)(b)(c) Successful Participation 42 CFR 493.1403 Laboratory Director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to successfully participate in a proficiency testing program for three consecutive events for amylase and two out of three events for prothrombin time in 2023 and 2024. The laboratory failed to successfully participate in three consecutive testing events in 2023 (event 3, 2023) and

	2024 (event 1 and event 2) resulting in a score of 0% for the analyte amylase as reported by the College of American Pathologist (CAP) (Refer to D2089). The laboratory failed to achieve satisfactory performance of 80% or greater for two out of three testing events in 2023 (event 2, 2023) and in 2024 (event 1). Results the analyte prothrombin time was 60% for event 2, 2023, and 60% for event 1, 2024 as reported by CAP (Refer to D2130).
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to successfully participate in a proficiency testing program for three consecutive events for amylase in 2023 and 2024. The laboratory failed to successfully participate in three consecutive testing events in 2023 (event 3, 2023) and 2024 (event 1 and event 2) resulting in a score of 0% for the analyte amylase as reported by the College of American Pathologist (CAP) (Refer to D2089). Findings included: 1. Review of the "Casper Report 0155D," run date 8/20/2024 indicated a score of 0% for event 3 2023, 0% for event 1 2024 and 0% for event 2 2024 for amylase as reported by the CAP. 2. Upon request for information on proficiency testing for 2023 and 2024 for amylase, via email on 8/22/2024 at 3:16 pm, SP-1 (Technical Consultant) provided a document "Proficiency Testing - Unsuccessful Event Investigation Report". 3. The "Proficiency Testing - Unsuccessful Event Investigation Report", reviewed by the laboratory director on 4/30/2024, documented on page 3 of 4 in the conclusion/ summary that the "site had ceased testing in August of 2023..." and CAP had not been notified. 4. Review of the "Clinical Laboratory Improvement Amendments (CLIA) Application for Certification" Form CMS 116, signed by the laboratory director on 3/8/2024, indicated amylase was listed as being performed by the laboratory. 5. Upon request for additional information on proficiency testing scores for amylase, via email on 9/11 /2024 at 12:22 pm, SP- 1 (Technical Consultant) provided CAP evaluations for C-B 2024. 6. Review of the CAP Evaluation for "C-B 2024 General Chemistry /Therapeutic Drugs", original evaluation date 7/2/2024, detailed the following for amylase: a) Page 8 of 10 "CMS Performance Summary for Analytes Regulated under the Clinical Laboratory Improvement Amendments of 1988": 1.) Proficiency Event 2023 3 had a score of 0/5 for 0%. 2.) Proficiency Event 2024 1 had a score of 0/5 for 0%. 3.) Proficiency Event 2024 2 had a score of 0/5 for 0% b) Page 5 of 10 "Evaluation and Comparative Method Statistics" indicated five specimens had been submitted to the laboratory and had noted "See Note [42]". c) Page 1 of 10 elaborated on exception code "[42]" equals "No credit assigned due to absence of response."
D2130	HEMATOLOGY CFR(s): 493.851(f)

	Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to achieve satisfactory performance of 80% or greater for two out of three testing events in 2023 (event 2, 2023) and in 2024 (event 1, 2024). Results the analyte prothrombin time were 60% for event 2, 2023, and 60% for event 1, 2024 as reported by CAP. Findings included: 1. Review of the "Casper Report 0155D," run date 8/20/2024 indicated a score of 60% for event 2 2023, 60% for event 1 2024 for prothrombin time as reported by the CAP. 2. Upon request for information on proficiency testing for 2023 and 2024 for prothrombin time, via email on 8/22/2024 at 3:16 pm, SP-1 (Technical Consultant) provided four documents "Proficiency Testing - Unsuccessful Event Investigation Report" for WP3-B 2023, the CAP evaluations for WP3-B 2023 page 2 of 2, "Proficiency Testing - Unsuccessful Event Investigation Report" for WP3- A 2024 and the CAP evaluation for WP3-A 2024 page 2. 3. The "Proficiency Testing - Unsuccessful Event Investigation Report", reviewed by the laboratory director on 6/23 /2023, documented on page 1 of 4 under unacceptable results that two out of five samples had been unacceptable. for event 2, 2023. 4. The CAP evaluation for WP3-B 2023 WB Prothrombin time/INR, I-Stat original evaluation date 5/30/2023, showed two out of five specimens were unacceptable. Giving a score of 60%. 5. The "Proficiency Testing - Unsuccessful Event Investigation Report", reviewed by the laboratory director on 4/30/2024, documented on page 1 of 4 under unacceptable results that two out of five samples had been unacceptable. for event 1, 2024. 6. The CAP evaluation for WP3-A 2024 WB Prothrombin time/INR, I-Stat original evaluation date 3/4/2024, showed two out of five specimens were unacceptable. Giving a score of 60%.
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 interview, the laboratory director failed to ensure the laboratory successfully participated in a proficiency testing program for three consecutive events for amylase and two out of three events for prothrombin time in 2023 and 2024. The laboratory failed to successfully participate in three consecutive testing events in 2023 (event 3, 2023) and 2024 (event 1 and event 2) resulting in a score of 0% for the analyte amylase as reported by the College of American Pathologist (CAP) and failed to achieve satisfactory performance of 80% or greater for two out of three testing events in 2023 (event 2, 2023) and in 2024 (event 1). Results the analyte prothrombin time was 60% for event 2, 2023, and 60% for event 1, 2024 as reported by CAP (Refer to 6016).
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory director failed to ensure the laboratory successfully participated in a proficiency testing program for three consecutive events for amylase and two out of three events for prothrombin time in 2023 and 2024. The laboratory failed to successfully participate in three consecutive testing events in 2023 (event 3, 2023) and 2024 (event 1 and event 2) resulting in a score of 0% for the analyte amylase as reported by the College of American Pathologist (CAP) and failed to achieve satisfactory performance of 80% or greater for two out of three testing events in 2023 (event 2, 2023) and in 2024 (event 1). Results the analyte prothrombin time was 60% for event 2, 2023, and 60% for event 1, 2024 as reported by CAP. Findings included: 1. Review of the "Casper Report 0155D," run date 8/20/2024 indicated the following scores: a) 0% for event 3 2023, 0% for event 1 2024 and 0% for event 2 2024 for amylase as reported by the CAP. b) 60% for event 2 2023, 60% for event 1 2024 for prothrombin time as reported by the CAP. 2. Upon request for information on proficiency testing for 2023 and 2024 for amylase, via email on 8/22/2024 at 3:16 pm, SP-1 (Technical Consultant) provided the following documents: a) "Proficiency Testing - Unsuccessful Event Investigation Report" for amylase reviewed by the laboratory director on 4/30/2024. b) Proficiency Testing - Unsuccessful Event Investigation Report" for WP3-B 2023 for prothrombin time, c) The CAP evaluations for WP3-B 2023 page 2 of 2 for prothrombin time, d) "Proficiency Testing - Unsuccessful Event Investigation Report" for WP3- A 2024 for prothrombin time, and e) the CAP evaluation for WP3-A 2024 page 2 for prothrombin time. 3. The "Proficiency Testing - Unsuccessful Event Investigation Report", reviewed by the laboratory director on 4/30/2024, documented on page 3 of 4 in the conclusion/ summary that the "site had ceased testing in August of 2023..." and CAP had not been notified. 4. The "Proficiency Testing - Unsuccessful Event Investigation Report", reviewed by the laboratory director on 6/23/2023, documented on page 1 of 4 under unacceptable results that two out of five samples had been unacceptable. for event 2, 2023. 5. The CAP evaluation for WP3-B 2023 WB Prothrombin time/INR, I-Stat original evaluation date 5/30/2023, showed two out of five specimens were unacceptable. Giving a score of 60%. 6. The "Proficiency Testing - Unsuccessful Event Investigation Report", reviewed by the laboratory director on 4/30/2024, documented on page 1 of 4 under unacceptable results that two out of five samples had been unacceptable. for event 1, 2024. 7. The CAP evaluation for WP3-A 2024 WB Prothrombin time/INR, I-Stat original evaluation date 3/4/2024, showed two out of five specimens were unacceptable. Giving a score of 60%. 8. Review of the "Clinical Laboratory Improvement Amendments (CLIA) Application for Certification" Form CMS 116, signed by the laboratory director on 3/8/2024, indicated amylase was listed as being performed by the laboratory. 9. Upon request for additional information on proficiency testing scores for amylase, via email on 9/11 /2024 at 12:22 pm, SP- 1 (Technical Consultant) provided CAP evaluations for C-B 2024. 10. Review of the CAP Evaluation for "C-B 2024 General Chemistry /Therapeutic Drugs", original evaluation date 7/2/2024, detailed the following for amylase: a) Page 8 of 10 "CMS Performance Summary for Analytes Regulated under the Clinical Laboratory Improvement Amendments of 1988": 1.) Proficiency Event

	2023 3 had a score of 0/5 for 0%. 2.) Proficiency Event 2024 1 had a score of 0/5 for 0%. 3.) Proficiency Event 2024 2 had a score of 0/5 for 0% b) Page 5 of 10 "Evaluation and Comparative Method Statistics" indicated five specimens had been submitted to the laboratory and had noted "See Note [42]". c) Page 1 of 10 elaborated on exception code "[42]" equals "No credit assigned due to absence of response." .