Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2256543	12/30/2024
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Health Floyd At Jefferson Ridge	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 12/30/2024. The following condition-level deficiencies were found to be out of compliance: D2016- 42 C.F.R. 493.803 Condition: Successful participation (proficiency testing) D6000-42 C. F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; 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 surveyor proficiency testing (PT) desk review of the laboratory PT records, the College of American Pathologists (CAP) Evaluation Reports, and CASPER Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data

	system, and emails from the Technical Consultant (SP-1) on 12/19/2024 and 12/30 /2024, the laboratory failed to achieve satisfactory performance in four consecutive events (one of three events in 2023, and three of three events in 2024) resulting in unsuccessful participation in the subspecialty of Routine Chemistry for the analyte of Amylase in 2023 and 2024. (Refer to D2089).
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) (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 surveyor proficiency testing (PT) desk review of the laboratory PT records, the College of American Pathologists (CAP) Evaluation Reports, and CASPER Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and emails from the Technical Consultant (SP-1) on 12/19/2024 and 12/30 /2024, the laboratory failed to achieve satisfactory performance in four consecutive events (one of three events in 2023, and three of three events in 2024) resulting in unsuccessful participation in the subspecialty of Routine Chemistry for the analyte of Amylase in 2023 and 2024. 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 CAP. 2. Upon request for information on PT 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..." 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 PT 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 report 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." 7. Review of the "Casper Report 0155D," run date 12/17/2024 indicated a score of 0% for event 3 2023, 0% for event 1 2024, 0% for event 2 2024, and 0% for event 3 2024 for amylase as reported by the CAP. 8. Upon request for additional

	information on proficiency testing scores for amylase, via email on 12/17/2024 at 2:59 pm, SP-1 (Technical Consultant) confirmed the 0% score and indicated they had not communicated with CAP that they were no longer testing for amylase. 9. Upon requests for a copy of the CAP summary for event 3, 2024, via emails sent on 12/17 /2024 at 4:39 pm, 12/19/2024 at 10:43 am, and 12/30/2024 at 8:40 am, SP-1 (Technical Consultant) provided the results on 12/30/204 at 11:54 am. 10. Review of the CAP Evaluation for "C-C 2024 General Chemistry/Therapeutic Drugs", original evaluation date 11/1/2024, 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% 4.) Proficiency Event 2024 3 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 for Amylase, serum 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."
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 surveyor proficiency testing (PT) desk review of the laboratory PT records, the College of American Pathologists (CAP) Evaluation Reports, CASPER Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and emails from the Technical Consultant (SP-1) on 12/19/2024 and 12/30/2024, the laboratory director failed to ensure that the laboratory successfully participated in four consecutive events (one of three events in 2023, and three of three events in 2024) in the subspecialty of Routine Chemistry for the analyte of Amylase in 2023 and 2024, and failed to provide overall management and direction of the laboratory services. Refer to D6016 & D6019.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on surveyor proficiency testing (PT) desk review of the laboratory PT records, the College of American Pathologists (CAP) Evaluation Reports, CASPER Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and emails from the Technical Consultant (SP-1) on 12/19/2024 and 12/30/2024, the laboratory director failed to failed to ensure successful participation in an HHS approved proficiency testing program. and failed to ensure the overall quality of the laboratory services provided. Refer to D2089.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) 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 surveyor proficiency testing (PT) desk review of the laboratory PT records, the College of American Pathologists (CAP) Evaluation Reports, CASPER Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and emails from the Technical Consultant (SP-1) on 12/19/2024 and 12/30/2024, the laboratory director failed to ensure an approved corrective action plan was followed when PT results were found to be unacceptable. Refer to D2089.