Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2104538	(X3) Date Survey Completed 03/28/2024
Name of Provider or Supplier Jackson Hospital & Clinic, Inc	**Street Address, City, State** 2175 Us Hwy 31 N, Deatsville, AL	

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 was conducted on 3/28/2024 and the following conditions were not met: D2016 - 42 C.F.R 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
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 a review of Proficiency Testing records and an interview with the Technical Consultant, the laboratory failed to achieve satisfactory performance in two of three consecutive testing events for the specialty of Hematology for White Blood Cell Differential (WBC), Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB), and Platelets (PLT). The findings include: 1. Refer to D2130 2. Refer to D2131

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 a review of Proficiency Testing (PT) records and an interview with the Technical Consultant, the laboratory failed to achieve satisfactory performance for two out of three consecutive PT events. This was noted for Hematology 3rd Event in 2022 and Hematology 1st Event in 2023. The findings include: 1. A review of PT records revealed the laboratory received a score of 0% for White Blood Cell Differential (WBC), Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB), and Platelets (PLT) for the Hematology 3rd PT event in 2022. The laboratory received no score for the Hematology 1st event in 2023 as a result of not submitting results to the PT provider. 2. During an interview on 3/28/2024 at 12:00 PM, the Technical Consultant confirmed the above findings.
D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing (PT) records and an interview with the Technical Consultant, the laboratory failed to achieve satisfactory performance for two out of three consecutive PT events. This was noted for Hematology 3rd Event in 2022 and Hematology 1st Event in 2023. The findings include: 1. A review of PT records revealed the laboratory received a score of 0% for White Blood Cell Differential (WBC), Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB), and Platelets (PLT) for the Hematology 3rd PT event in 2022. The laboratory received no score for the Hematology 1st event in 2023 as a result of not submitting results to the PT provider. 2. During an interview on 3/28/2024 at 12:00 PM, the Technical Consultant confirmed the above findings.
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 a review of Proficiency Testing (PT) records and an interview with the Technical Consultant, the Laboratory Director failed to provide overall management and direction of laboratory services as required under Subpart H. The findings include: 1. Refer to D6016

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 a review of Proficiency Testing (PT) records and an interview with the Technical Consultant, the Laboratory Director failed to ensure PT samples were performed as required under Subpart H. This was noted for two consecutive PT events reviewed in 2022 and 2023. The findings include: 1. A review of PT records revealed the laboratory received a score of 0% for White Blood Cell Differential (WBC), Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB), and Platelets (PLT) Hematology 3rd PT event in 2022. The laboratory received no score for the Hematology 1st event in 2023 as a result of not submitting results to the PT provider. 2. During an interview on 3/28/2024 at 12:00 PM, the Technical Consultant confirmed the above findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of Personnel records and an interview with the Technical Consultant, the Technical Consultant failed to assess competency six months after initial training on the Beckman Coulter DxH 520 Hematology analyzer for Testing Personnel #2 and Testing Personnel #3. This was noted for two out of two previously qualified Testing Personnel from the date of the last survey, 7/20/2022, to the date of the current survey, 3/28/2024. The findings include: 1. A review of Personnel records revealed initial training for the Beckman Coulter DxH 520 for Testing Personnel #2 and #3 dated 9/14/2022. No evidence of a six month competency assessment was available for either Testing Personnel at the time of survey. 2. During an interview on 3/28/2024 at 12:00 PM, the Technical Consultant confirmed the above findings.