| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 04D0689677 | 01/25/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Baptist Health Family Clinic Ellsworth Road | 5428 Ellsworth Road, Suite A & B, Fort Smith, AR | |

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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| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>. Through a review of the "Coulter AcT Diff 2 Operator's Manual", the laboratory's procedure manual, the Patient WBC/Diff Review reports for December 2017 and January 2018, patient CBC reports, as well as interviews with staff, it was determined the laboratory failed to follow the manufacturer's instructions for flags on patient results. As evidenced by: A. The "Coulter AcT Diff 2 Operator's Manual" states "that if the patient result has a 1, 2, 3, 4, or M flag the laboratory should "Verify results according to your laboratory's protocol." B. A review of the laboratory procedure manual revealed the protocol for addressing flags which states "any flag that appears in patient result must be reviewed by the laboratory tech. If a flag calls for a slide review, the specimen must be sent to Sparks Main Lab for review. The following flags require a slide review: 1,2,3,4 or M. Patient results cannot be reported with flags." C. A review of the patient WBC/DIFF review report revealed ten of forty-four patients analyzed from 12/15/2017 to 12/26/2017 had flags reported on their Complete Blood Count (CBC) results: on 12/15/2017 patient #96443 had flags on the WBC differential; patient #964511 had flags on the Lymphocyte and Granulocyte portion of the WBC differential; patient #499672 had flags on the WBC differential; patient #565129 had flags on the WBC differential; patient #735520 had flags on the WBC differential; patient #79183 had flags on the WBC differential; patient #800995 had flags on the WBC differential; patient #517565 had flags on the WBC differential; patient #814453 had flags on the WBC differential and patient #774835 had flags on the WBC differential. D. A review of the patient WBC/DIFF review report revealed |

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| | twelve of fifty-one patients analyzed from 01/02/2018 to 01/08/2018 had flags reported on their CBC results: on 01/02/2018 patient #930175 had flags on the Monocyte and Granulocyte portion of the WBC differential; patient #457559 had flags on the WBC differential; patient #412924 had flags on the WBC differential; patient #912411 had flags on the Monocytes and Granulocyte portion of the WBC differential; patient #744392 had flags on the Monocytes and Granulocyte portion of the WBC differential; patient #878191 had flags on the Monocytes and Granulocyte portion of the WBC differential; patient #788933 Monocytes and Granulocyte portion of the WBC differential; patient #968778 Monocytes and Granulocyte portion of the WBC differential; patient #442882 had flags on the WBC differential; patient #442882 had flags on the WBC differential; patient #421173 Monocytes and Granulocyte portion of the WBC differential; patient #464855 had flags on the WBC differential and patient #50364 had flags on the WBC differential. E. In an interview at 10:30 on 01/25/2018, the technical consultant (as listed on the form CMS-209) confirmed the laboratory failed to follow its policy for addressing flagged CBC reports from the AcT Diff 2. |