| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>04D2170189 | (X3) Date Survey Completed<br>10/20/2022 |
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| Name of Provider or Supplier<br>Mercy Springdale Hod | Street Address, City, State<br>4600 Mercy Lane, Springdale, 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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| **D5783** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(2)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.<br><br>This STANDARD is not met as evidenced by:<br>. Through review of quality control (QC) policy and procedure , QC results for July 2022 , lack of documentation and interviews with laboratory staff it was determined that the laboratory failed to evaluate patient results back to the last successful performance of QC, on one of two occasions when QC failed criteria for acceptability. Findings follow: A) Review of the laboratory policy and procedure revealed that action is to be taken when QC fails criteria for acceptability and "1 -3S a run is rejected when a single measurement exceeds the mean plus or minus 3SD and 2- 2S a run is rejected when 2 consecutive control measurements exceed the mean plus or minus 2SD control limit. B) Review of QC records for NT-proBNP test revealed that on 7/18 at 01:03 am Biorad Level 3 Control lot # 67650 with acceptable limits of 2625 to 3133 was resulted as 2558 flagged (1-2S), as 2567 flagged (1-2S) at 01:38 a. m., as 2546 flagged (2-2S) at 0232 a.m. C) Review of documentation of corrective action for the event identified above revealed that the test system had been recalibrated which indicated a change in the test system operation. D) Review of QC results revealed the previous acceptable QC results for NT-proBNP testing was performed on 7/17/22 at 01:35 am. E) Upon request, the laboratory was unable to provide documentation that the patient testing performed during the interval identified in the citation above had been evaluated. G) In an interview on 10/20/22 at 09:32 am |

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| | the laboratory staff member (#19 on the CMS 209 form) stated that the laboratory had initiated a policy requiring results to be evaluated back to the last successful QC when a 2-2S or 1-3S QC failure required corrective action that effectively changed the testing system in May of 2022 and confirmed that the test identified in the citation above had not been evaluated and should have been. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Through a review of one Laboratory Result report when the test was referred to an outside laboratory and interviews with laboratory personnel it was determined the laboratory test report failed to include the address of the laboratory location where the test was performed. Survey findings include: A) In an interview on 10/19/22 at 09:42 a.m., the laboratory staff member ( #19 on the CMS 209 form) stated that the laboratory's coagulation analyzer was out of order on 11/1/21 and all coagulation testing was referred to Mercy Hospital in Rogers AR. B) Upon request, the laboratory produced results of a D-Dimer assay that was referred on 11/1/21 on patient 1501467484. C) Review of the report for the D-Dimer identified above revealed that the "Resulting Labs : Mercy Laboratory Services Springdale CLIA # 04D2170189". D) In an interview at 09:42 a.m. on 10/19/22 the laboratory staff member ( #19 as listed on the form CMS-209) confirmed the performing laboratory listed on the report was not the laboratory that performed the testing on the samples. |