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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>45D2024578  | <b>(X3) Date Survey Completed</b><br><br>04/24/2025 |
| <b>Name of Provider or Supplier</b><br><br>Hopkins Minor Emergency Center Llc  | <b>Street Address, City, State</b><br><br>106 Hodge St, Sulphur Springs, TX |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D0000</b>              | The laboratory was found to be in compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a recertification survey completed on April 24, 2025.   |
| <b>D5447</b>              | <p><b>CONTROL PROCEDURES</b><br/>CFR(s): 493.1256(d)(3)(i)(g)</p> <p>(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory policy, laboratory quality control documentation, patient test results, and confirmed in interview, the laboratory failed to ensure that quality control (QC) was performed, and acceptable, before patient CBC testing for 30 patients performed on days where QC failed to be performed Sysmex Pochi-100i hematology analyzer for records reviewed in 2024. This is a repeat deficiency that was identified in an onsite recertification inspection performed on June 2, 2023. The findings included: 1. Review of the laboratory policy titled "Daily CBC QC" included the following instructions: "Daily CBC QC (Change controls every 14 days) .... If any numbers are out of range you will re-run the control until its [sic] brought into range." 2. Review of laboratory quality control documentation, and patient reports, for July through September 2024 included the following 18 days where CBC QC was not documented on the Sysmex pochi-100i analyzer before patient testing occurred: July 2024 included the following seven days and 10 patients with CBC testing when QC was not performed: Date: Patient ID's 07/11/2024: 2146, 2147 07/15/2024 : 2280 07/16/2024 : 2314 07/22/2024 : 2622 07/23/2024 : 2705 07/24/2024 : 2768 07/25/2024 : 2786, 2799, 841 August 2024 included the following eight days and 16 patients with CBC testing when QC was not performed: Date: Patient ID's 08/01/2024: 1379, 3153 08/03/2024 : 2218, 3256 08/02/2024 : 2642, 3196 08/05/2024 : 3325, 3345,3275, 3347, 3280 08/10/2024 : 1645, 3602 08/16/2024 : 2590 08/19/2024 : 4022 08/22/2024 : 4203 September 2024 included the following three days and four patients with CBC</p> |

testing when QC was not performed: Day: Patient ID's 09/14/2024: 5054, 5047 09/19/2024: 5199 09/23/2024: 195889 3. In an interview on 4/24/2025 at 11:50 hours, in the breakroom, the technical consultant confirmed there was no QC documentation for the Sysmex Pochi-100 on the above days where patient testing was performed. KEY: CBC - Complete blood count