

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0921240	(X3) Date Survey Completed 11/02/2022
Name of Provider or Supplier Grace Family Practice Clinic, Pc	Street Address, City, State 1716 Parr Ave Ste D, Dyersburg, TN	
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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient records and interview with the technical consultant, the laboratory failed to ensure provider orders for performing patient complete blood count with differential (CBC with Diff) for two of four patient reviewed from 2021 and 2022. The findings include: 1. Review of patient records revealed the following: Patient #376- CBC with Diff reported on 09/22/21, no order in the patient chart for CBC with Diff. Patient #2085-CBC with Diff reported on 08/15/22, no order in the patient chart for CBC with Diff. 2. Interview on 11/02/22 at 5 pm with the technical consultant confirmed the laboratory performed patient testing for CBC with Diff in 2021 and 2022 for two of four patient records reviewed without a provider order.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of final patient complete blood count (CBC) results, the manufacturer procedure manual, patient data logs and interview with the technical consultant, the laboratory failed to follow manufacturer instructions for repeat testing</p>

when instrument flagged results were present for four of four patient reviewed from 2021 and 2022. The findings include: 1. Review of patient numbers 18028, 376, 2579, and 2085 final CBC report revealed the result for platelet was flagged as AG*. 2. Review of the manufacturer procedure manual in the section for flagged results revealed the following: "When histogram flags are displayed, perform analysis again." 3. Review of patient data logs from the CBC instrument revealed the CBC was not repeated for any of the four patients. 4. Interview with the technical consultant on 11/02/22 at 5 pm confirmed the laboratory failed to follow the manufacturer instructions for repeat testing of flagged platelet results in 2021 and 2022 for four of four patients reviewed.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the manufacturer operating manual, lack of documentation and interview with the technical consultant, the laboratory failed to monitor the humidity in the area where the Sysmex XP 300 complete blood count (CBC) instrument was in operation in 2021 and 2022. The findings include: 1. Observation of the laboratory on 11/02/22 at 1:15 pm revealed the Sysmex XP 300 instrument in use for patient testing for CBC. 2. Review of the manufacturer's operating manual revealed a humidity range of 30% to 85% for operation of the instrument. 3. Review of environmental records from 2021 and 2022 revealed no documentation that the humidity was being monitored. 4. Interview with the technical consultant on 11/02/22 at 5 pm confirmed the laboratory did not monitor the humidity in the area where the Sysmex XP 300 CBC instrument was located in 2021 and 2022.