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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>49D0704407 | <b>(X3) Date Survey Completed</b><br>02/10/2021 |
| <b>Name of Provider or Supplier</b><br>Centra Danville Medical Center  | <b>Street Address, City, State</b><br>414 Park Avenue, Danville, VA    |   |
| 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>              | An announced CLIA Recertification on-site survey was conducted at Centra Danville Medical on February 10, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with laboratory conducted on January 21, 2021 with off-site record review of documentation and a follow-up email on February 5 & 8, 2021. Specific deficiencies cited are as follows:   |
| <b>D5429</b>              | <p><b>MAINTENANCE AND FUNCTION CHECKS</b><br/>CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on the review of laboratory maintenance logs, manufacturer operator's guide, lack of documentation and interview with the primary testing personnel and technical consultant, the lab failed to perform the thermal probe checks for the iSTAT hand-held analyzer twice a year in 2019 and 2020. Findings include: 1. The laboratory utilizes the iSTAT hand-held analyzer to perform Troponin I and B-type Natriureic Peptide (BNP) chemistry tests, categorized as moderate complexity testing. 2. Review of the laboratory maintenance logs on February 5, 2021 revealed lack of documentation of the thermal probe checks for the analyzer. The inspector requested to review documentation of thermal probe checks and the lab provided documentation of the specified maintenance performed on 09/16/20 at the date of on-site survey on February 10, 2021. No other documentation was available for review. In an interview with the primary testing personnel and technical consultant on February 10, 2021 at approximately 10 AM, they stated that the lab staff did not realize that the thermal probe checks were required and that the policy was updated to include the procedure for performing the checks on 05/22/20. 3. Review of the manufacturer operator's</p> |

guide revealed the following statement, "Procedures- Quality Control- Thermal Probe Check (14-19): Check the thermal probes on each analyzer twice a year." 4. An interview with the technical consultant on February 10, 2021 at approximately 11:20 AM confirmed the findings.