

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0723096	(X3) Date Survey Completed 12/18/2019
Name of Provider or Supplier Sunrise Diagnostic	Street Address, City, State 22347 Northwestern Pike, Romney, WV	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS 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: Based on a tour of the laboratory, a review of the laboratory current equipment list, a review of laboratory preventative maintenance (PM) records, and an interview with testing personnel 1 (TP1), the laboratory failed to have annual preventive maintenance performed for all the equipment and instruments used in patient testing, including those that are peripherally involved. Findings: 1. A tour of the laboratory and an inspection of laboratory equipment and instruments identified annual service stickers from Medical Equipment Source, LLC with service dates of 1/23/18 and 1/24/18, with next annual service due by 1/23/19 and 1/24/19, documented on the following equipment and instruments: a. Tissue Processor Tissue Tek VIP6-A1 (SN 60300681-1011) b. Embedding Center Tissue Tek 4710 (SN 47101210) c. Microtome Leica RM2135 (SN 050029135) d. Water Bath 1 Premiere XH-1003 (SN N224) e. Water Bath 2 Premiere XH-1003 (SN N232) f. Stainer Leica T25015 (SN 045638880) g. Coverslipper Leica CV5030 (SN 047836700) h. Paraffin Dispenser Premiere XH4002 (SN N116) i. Slide Drying Oven Quincy Lab 20GC (SN G2-6092) j. Fume Hood 1 Air Filtronics H53000 (SN 13086) k. Fume Hood 2 Air Filtronics H53000 (SN 13085) l. Wax Trimmer Premiere XH-90 (SN N043) m. Cooling Plate Tissue Tek 4709 (SN S-47091210) 2. A tour of the laboratory and an inspection of laboratory equipment and instruments identified annual service stickers from Medical Equipment Source, LLC with service dates of 12/illegal day/2012 on a total quantity of 3 Eaton 9130 backup battery power towers for Tissue Tek VIP6-A1 Tissue Processor. No documentation of any other annual service or preventative maintenance checks could be located. 3. No documentation of the performance of 2019 annual PM or service by</p>

Medical Equipment Source, LLC could be located for the equipment and instruments listed at finding 1 (a thru m). 4. A review of 2018 and 2019 laboratory PM logs identified daily, weekly, and monthly PM being performed and documented by testing personnel 1 (TP1) on all equipment and instruments utilized in patient testing, including those peripherally involved. 5. An interview with TP1, on 12/18/19 at approximately 10:20 AM, confirmed that Medical Equipment Source, LLC is the company who performs the annual maintenance on all the equipment and instruments utilized in patient testing and that the 2019 annual service had not been performed.

D6095

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory instrument and equipment preventative maintenance (PM) logs and a tour of the laboratory, the laboratory director failed to ensure the analytic performance of each test system by not adhering to the manufacturer requirements of annual preventative service and maintenance for the instruments and equipment utilized in the laboratory for patient testing. Findings: 1. A review of 2018 and 2019 laboratory PM logs identified daily, weekly, and monthly preventative maintenance performed on the instruments and equipment utilized in patient testing. 2. A tour of the laboratory and an inspection of laboratory equipment and instruments identified annual service stickers from Medical Equipment Source, LLC with service dates of 1/23/18 and 1/24/18, with next annual service due by 1/23 /19 and 1/24/19, documented on the following equipment and instruments: a. Tissue Processor Tissue Tek VIP6-A1 (SN 60300681-1011) b. Embedding Center Tissue Tek 4710 (SN 47101210) c. Microtome Leica RM2135 (SN 050029135) d. Water Bath 1 Premiere XH-1003 (SN N224) e. Water Bath 2 Premiere XH-1003 (SN N232) f. Stainer Leica T25015 (SN 045638880) g. Coverslipper Leica CV5030 (SN 047836700) h. Paraffin Dispenser Premiere XH4002 (SN N116) i. Slide Drying Oven Quincy Lab 20GC (SN G2-6092) j. Fume Hood 1 Air Filtronics H53000 (SN 13086) k. Fume Hood 2 Air Filtronics H53000 (SN 13085) l. Wax Trimmer Premiere XH-90 (SN N043) m. Cooling Plate Tissue Tek 4709 (SN S-47091210) No documentation of annual service and maintenance for 2019 by either Medical Equipment Source, LLC or another company, could be located. 3. A tour of the laboratory and an inspection of laboratory equipment and instruments identified annual service stickers from Medical Equipment Source, LLC with service dates of 12/illegible day/2012 on a total quantity of 3 Eaton 9130 backup battery power towers for Tissue Tek VIP6-A1 Tissue Processor. No documentation of any other annual service or preventative maintenance checks could be located. 4. An interview with TP1, on 12/18/19 at approximately 10: 30 AM, confirmed that no annual service or maintenance on the laboratory instruments and equipment had been performed in 2019.