| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number

15D0353522 | (X3) Date Survey Completed

01/15/2019 |
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| **Name of Provider or Supplier**

Cytology Pathology Services, Inc | **Street Address, City, State**

5865 N Michigan Rd, Indianapolis, IN | |

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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation, interview, and record review, the laboratory failed to document preparation and expiration dates for two of two Papanicolaou stains: OG-6 and Eosin Azure (EA), in use and prepared by the laboratory. Annual cytology specimens=488. Findings include: 1. On 01/14/19 at 1:55 PM, a tour of the lab was conducted with SP-1, and the following materials were observed in the cytology cabinet, available for use: a. An opened bottle of Papanicolaou, OG-6 stain, with no preparation or expiration dates. b. An opened bottle of Papanicolaou, Eosin Azure (EA) stain, with no preparation or expiration dates. 2. In interview on 01/14/19 at 2:03 PM, SP-2 acknowledged there were no preparation and expiration dates, on the bottles labeled "OG-6" and "EA". SP-2 indicated these bottles contained stains that were mixed in the lab. 3. Review of the lab manual with the title page "CYTOLOGY STAIN FORMULAS", no effective date, included "EA - 4 LITER" and "OG-6- 4 LITER" stains, but did not include expiration dates/shelf-life time period. 4. Medical record review indicated patients (PT) #11-#20 had cytology specimen staining with Papanicolaou, OG-6 and Papanicolaou, Eosin Azure (EA) stains, on the following days: PT#11=11/30/18 PT#12=11/26/18 PT#13=11/06/18 PT#14=10/26/18 PT#15=10/11/18 PT#16=10/01/18 PT#17=09/20/18 PT#18=07/16/18 PT#19=05/05/18 PT#20=02/16/18 |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS |

CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:
Based on observation, interviews, and record review, the laboratory failed to document compliance with manufacturer's maintenance requirements for one of one Thermo Fishers Scientific HM 325-2 Microtome. Annual histology specimens=5,845. Findings include: 1. On 01/15/19 at 9:05 AM, during lab tour, a Thermo Fishers Scientific HM 325-2 Microtome was in operation. The only documentation of maintenance was a maintenance sticker labeled "Microm/HM-325, 10/13/14". 2. In interview on 01/15/19 at 9:13 AM, SP-4 acknowledged the Thermo Fishers Scientific HM 325-2 Microtome had not been serviced in a very long time. SP-4 indicated there was a manual from 1993, but was unable to locate it. 3. In interview on 01/15/19 at 11:30 AM, SP-3 (laboratory director), acknowledged the Thermo Fishers Scientific HM 325-2 Microtome had not been serviced in a long time. 4. Medical record review indicated patients (PT) #1-#10 had histology specimen processing with the Thermo Fishers Scientific HM 325-2 Microtome, on the following days: PT#1=01/02/18 PT#2=03/15/18 PT#3=06/11/18 PT#4=09/27/18 PT#5=10/01/18 PT#6=10/17/18 PT#7=11/08/18 PT#8=11/28/18 PT#9=12/12/18 PT#10=12/12/18 5. Review of "Rotary Microtome #M325-2 Instruction Manual" (no revision date), confirmed in "Part 5 Maintenance and Care", a recommendation for routine maintenance to be performed by a trained service technician once a year. It is also required that the battery be changed by the service technician after five years.