

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1019019	(X3) Date Survey Completed 02/15/2018
Name of Provider or Supplier Boro Park Obgyn, Pc	Street Address, City, State 5925 15th Avenue, Brooklyn, NY	
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
D5633	<p>CYTOLOGY CFR(s): 493.1274(d)(1)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Cytology procedure manual and confirmed in an interview with the laboratory supervisor, the laboratory failed to establish a written procedure for the maximum workload limits for individuals who perform primary screening. FINDINGS: 1. The laboratory supervisor confirmed on February 14, 2018 at approximately 11:00 AM, the laboratory failed to establish a written policy or procedure for the maximum workload limits for each individual who performs primary screening. 2. The written procedure titled: "SLIDE VOLUME RECORD (PRODUCTIVITY SHEET)" stated, "The maximum number of slides must not exceed the workload limit set by the New York State Department of Health." This statement does not establish a workload limit and did not describe how the technical supervisor would establish the workload limit for each individual who performs primary screening. a. the laboratory supervisor stated, " That a workload limit of 80 slides/24 hour period was established but it was not written in a policy.</p>
D5635	<p>CYTOLOGY CFR(s): 493.1274(d)(1)(i)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(i) The workload limit is based on the individual's performance using evaluations of the following: (d)(1)(i)(A) Review of 10 percent of the cases interpreted as negative for the conditions defined in paragraph (e)(1) of this section. (d)(1)(i)(B) Comparison of the individual's interpretation with</p>

the technical supervisor's confirmation of patient smears specified in paragraphs (e)(1) and (e)(3) of this section.

This STANDARD is not met as evidenced by:

Based on the review of the cytology procedure manual and confirmed in an interview with the laboratory supervisor, the laboratory failed to establish a written procedure for workload limits based on the cytotechnologists performance and skills to screen gynecologic cytology slides. FINDINGS: The laboratory supervisor confirmed on February 14, 2018 at approximately 11:30 AM that the laboratory failed to provide a written policy or procedure based on the cytotechnologists performance and skills to screen gynecologic cytology slides.

D5637

CYTOLOGY

CFR(s): 493.1274(d)(1)(ii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

This STANDARD is not met as evidenced by:

Based on the review of the cytology procedures, laboratory records and confirmed in an interview with the laboratory supervisor, the laboratory failed to establish and follow written policies and procedures to ensure that workload limits are reassessed at least every 6 months and adjusted when necessary for each individual. FINDINGS: 1. The laboratory procedure titled " Biannual Cytotechnologists Diagnostic Assessment" did not state if, when or how workload limits would be reassessed or adjusted for each individual who performs primary screening of cytology slides. 2. There were no laboratory records to document that workload records were reassessed by the previous technical supervisor at least every six months and adjusted when necessary for 2016 and 2017 for the two cytotechnologists, who perform primary screening of the gynecologic cytology slides.

D5639

CYTOLOGY

CFR(s): 493.1274(d)(2)(i)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the Following: (d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition-- (d)(2)(i) The maximum number of 100 slides is examined in no less than an 8-hour workday;

This STANDARD is not met as evidenced by:

Based on surveyor's review of the cytology procedure manual and confirmed in an interview with the laboratory supervisor, the laboratory failed to establish written policies and procedures that ensure the maximum number of slides examined in a 24-hour period does not exceed 100 slides regardless of the site or location. FINDINGS: 1. The laboratory supervisor confirmed on February 14, 2018 at approximately 11:30 AM, that the laboratory failed to establish written policies and procedures that ensure

the maximum number of slides examined in a 24-hour period does not exceed 100 slides regardless of the site or location. 2. . The current workload worksheet does not define the type of slides screened each day as Full Manual Review (FMR) or Field of View (FOV) or both. The form includes date #GYN cases/slides and Total # of GYN cases/slides and total hours. 3. Surveyor performed a random reviewed the monthly workload sheets and found the following issues with maximum # of slides screened per hour. a. June 2016 total # of slides screened per hour 80 slides/5 hours for June 1,2,9,16,18,23,27,29,30 56 slides/3 hours for June 10 and 19 b. December 2016 total # of slides screened per hour 80 slides/5 hours for December 6, 8,13,15,20,22,27,29 61 slides/3 hours for December 18 72 slides/4.5 hours for December 31 c. March 2017 total # slides screened per hour 80 slides/5 hours for March 2,4,7,9,15,17,23,24,28,30 78 slides/5 hours for March 11 d. May 2017 total # slides screened per hour 80 slides /5 hours for May 2,16,23,24,26 80 slides/5.5 hours for May 9,17,18 69 slides/4 hours for May 3 80 slides/4.5 hours for May 6,20,31 e. September 2017 total # slides screened per hour 80 slides/4.5 hours for September 21 80 slides/5 hours for September 1,13,14,15,19,20,27, 80 slides/5.5 hours for September 28 f. November 2017 total # slides screened per hour 80 slides/4.5 hours for November 7,9,14,25 43 slides/3 hours for November 4 66 slides/3 hours for November 30 80 slides/4 hours for November 10 76 slides/4.5 hours for November 17 80 slides/5 hours for November 29 80 slides/5.5 hours for November 16 g. January 2018 total # slides screened per hour 80 slides/4.5 hours for January 5,16,30 80 slides/5 hours January 3,9,18,23, 80 slides/6 hours January 11 72 slides/5 hours January 19