Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658053	04/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Hospital De La Universidad De Puerto Rico	Ave 65th Infanteria Km 8 3, Carolina, PR	

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
D2044	MYCOLOGY CFR(s): 493.827(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on CAP Proficiency Testing Program records (2016,2017,2018) review and laboratory general supervisor interview on April 25, 2018 at 11:50 AM, it was determined that the laboratory failed to take and document remedial actions when it obtained a score of 80% results in mycology (yeast identification) specialty. The findings include: 1. On April 25, 2018 at 11:50 AM, the CAP Proficiency Testing Program records showed a score of 80% results for the yeast identification in the first testing event of year 2017. 2. Review of the laboratory remedial actions sheet did not include any remedial action taken nor documented. 3. The general supervisor confirmed on April 25, 2018 at 11:50 AM, that the laboratory did not take nor document remedial actions for this event.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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.

This STANDARD is not met as evidenced by:
1. Based on laboratory written procedure, cytology review log record (year 2017 and 2018) and cytotechnologist interview on April 25, 2018 at 9:25 AM, it was determined that the laboratory failed to follow written procedures to include the require information in 25 out of 25 cytology cases reviewed from January 11, 2017 to November 30, 2017. The findings include: a. The laboratory written procedures showed that the following information must be included in the cytology review log record: cytology number case, sample, collection date, diagnosis of the cytotechnologist, diagnosis (Dx) of the pathologist, results of the comparison, date of review and pathologist signature. b. On April 25, 2018 at 9:25 AM, the cytology review log record showed that the laboratory did not include the required information in 25 out of 25 cytology cases reviewed from January 11, 2017 to November 30, 2017: cytology sample information number date not documented FNA-02-17 01/11 /2017 Dx of the pathologist NG-09-17 01/19/2017 Dx of the pathologist NG-30-17 03 /23/2017 Dx of the pathologist NG-31-17 03/24/2017 Dx of the pathologist NG-32-17 03/23/2017 Dx of the pathologist NG-33-17 03/24/2017 Dx of the pathologist NG-34-17 03/24/2017 Dx of the pathologist NG-35-17 03/24/2017 Dx of the pathologist NG-90-17 09/08/2017 review date NG-91-17 09/09/2017 review date NG-92-17 09/09 /2017 review date NG-93-17 09/12/2017 review date CV-14-17 09/14/2017 review date FNA-27-17 09/13/2017 review date FNA-28-17 09/13/2017 review date NG-94-17 09/26/2017 review date NG-95-17 09/27/2017 review date NG-96-17 11/04/2017 Dx of the pathologist CV-015-17 11/06/2017 Dx of the pathologist NG-97-17 11/09 /2017 Dx of the pathologist NG-98-17 11/10/2017 Dx of the pathologist FNA-29-17 11/15/2017 Dx of the pathologist NG-99-17 11/23/2017 Dx of the pathologist CV-016-17 11/25/2017 Dx of the pathologist FNA-30-17 11/30/2017 Dx of the pathologist c. The cytotechnologist confirmed on April 25, 2018 at 9:25 AM, that the laboratory did not include the required information in 25 out of 25 cytology cases review from January 11, 2017 to November 30, 2017. 2. Based on lack of nongynecologic workload records, cytology procedures manual, cytology annual tests volume records (years 2016, 2017 and 2018) review and cytotechnologist interview on April 25, 2018 at 9:50 AM , it was determined that the laboratory failed to have a written procedure to document the nongynecologic slides workload and to establish the workload limit for the testing personnel (laboratory director and two pathologist) that examined and reported of the nongynecologic slides from January 2016 to March 2018. The findings include: a. The cytology annual tests volume records showed that the laboratory testing personnel (laboratory director and two pathologists) examined and reported 272 out of 272 nongynecological cases from January 2016 to March 2018. b. The laboratory did not document the nongynecologic slides workload nor evaluate the workload limit for these testing personnel (laboratory director and two pathologist) that examined the nongynecologic slides from January 2016 to March 2018. c. The cytology procedures manual did not have a written procedures to document the nongynecologic slide workload and to establish the workload limit for these testing personnel. d. The cytotechnologist confirmed on April 25, 2018 at 9:30 AM, that the laboratory did not have the required written procedures. 3. Based on routine chemistry (arterial blood gases) quality controls records reviewed (years 2016 to 2018) and laboratory general supervisor interview on April 25, 2018 at 11:00 AM, it was determined that the laboratory failed to evaluate and define twice a year the relationship between the automatic and manual calculation of the arterial blood gases (HCO3-, BE, tCO2 and %SO2) calculated values. The finding includes: 1. The laboratory uses Cobas 221b to perform Arterial blood gases (ABG's) patient' s samples tests. 2. The arterial blood gases quality control records were reviewed from January 2016 to April 2018. 3. The laboratory written policies established that the

	laboratory must verify each six months the relationship between the automatic and manual calculation of the arterial blood gases (HCO3-, BE, tCO2 and %SO2) calculated values since January 2016. 4. The laboratory general supervisor confirmed on April 25, 2018, that the laboratory failed to evaluate as establishes twice a year the relationship between the automatic and manual calculation of the arterial blood gases (HCO3-, BE, tCO2 and %SO2) calculated values since January 2016. 5. The laboratory processed and reported seven thousand seven hundred (7,700) arterial blood gases during this period.
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 lack of nongynecologic workload records, cytology procedures manual, cytology annual tests volume records (years 2016, 2017 and 2018) review and cytotechnologist interview on April 25, 2018 at 9:50 AM , it was determined that the laboratory failed to document and evaluate the workload of the testing personnel that examine 272 out of 272 nongynecologic slides from January 2016 to March 2018. The findings include: 1. The cytology annual tests volume records showed that the laboratory testing personnel (laboratory director and two pathologists) examined and reported 272 out of 272 nongynecological cases from January 2016 to March 2018. 2. The laboratory did not document the nongynecologic slides workload nor evaluate the workload limit for these testing personnel (laboratory director and two pathologist) that examine the nongynecologic slides from January 2016 to March 2018. 3. The cytology procedures manual did not have a written procedures to document the nongynecologic slide workload nor establish the workload limit for these testing personnel. Refer to D5401 (2). 4. The cytotechnologist confirmed on April 25, 2018 at 9:30 AM, that the laboratory did not document the nongynecologic slide workload nor evaluate the workload limits for those testing personnel from January 2016 to March 2018. Also stated that the laboratory did not have the written procedures for those requirements.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on quality assessment (QA) records review (years 2016-2018) and laboratory general supervisor interview on April 25, 2018 at 11:00 AM, it was determined that

	the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: 1. The laboratory written policies established that the laboratory must verify each six months the relationship between the automatic and manual calculation of the arterial blood gases (HCO3-, BE, tCO2 and %SO2) calculated values. 2. The laboratory failed to evaluate and define as establishes twice a year the relationship between the automatic and manual calculation of the arterial blood gases (HCO3-, BE, tCO2 and %SO2) calculated values. Refer to D5401.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on CAP Proficiency Testing Program records (2016,2017,2018) review and laboratory general supervisor interview on April 25, 2018 at 11:50 AM, it was determined that the laboratory director failed to follow a corrective action plan when the laboratory obtained a score of 80% results in mycology (yeast identification) specialty. Refer to D 2044.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on laboratory written procedure, cytology review log record (years 2017 and 2018), lack of nongynecologic workload records, cytology annual tests volume records (years 2016 to 2018) review and cytotechnologist interview on April 25, 2018 at 9:50 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for cytology analytic system. The findings include: 1. The laboratory director failed to ensure compliance with the analytic system requirements of cytology specialty. Refer to D 5401 (The laboratory did not follow written procedures to include the required information in 25 out of 25 cytology cases reviewed from January 11, 2017 to November 30, 2017. Refer to D 5639 (The laboratory did not document nor evaluate the workload of the testing personnel that examined 272 out of 272 nongynecologic slides from January 2016 to March 2018.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by:

	Based on Quality Assessment (QA) records review in 2016-2018 and laboratory general supervisor interview at 11:00 AM on April 25, 2018, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements for arterial blood gases test. Refer to D5791.