Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0862191	12/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Bryn Mawr Oral Pathology & Biopsy Service	3334 W Peterson Ave, Chicago, IL	

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
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, the lack of documentation and an interview with the laboratory director (LD); the laboratory failed to document each day of use, the intended reactivity of the staining materials for the Hematoxylin and Eosin (H&E) staining procedure performed for 11 out of 11 patients. Findings include: 1. The laboratory procedures manual and patients test log book were reviewed. 2. The laboratory sends its biopsies to a tissue processing laboratory for slide production. 3. Patients biopsies were selected from the log book for the following dates: *01/22 /2018; 03/28/2018; 06/01/2018; 08/21/2018; 10/11/2018; and 12/17/2018; *02/15 /2019; 04/22/2019; 07/02/2019; 09/12/2019; and 11/12/2019. 4. Further, review revealed the tissue processing laboratory that produced the slides did not provide H&E quality control records along with the slides for the above dates. 5. The laboratory failed to perform and document the quality of the H&E staining when reading the biopsy slides. 6. On a Recertification survey conducted on 12/11/2019 at 1: 15 PM, the LD confirmed the above findings and stated that he does check the H&E stain quality but does not document his evaluation.
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 record review and an interview with the laboratory director (LD); the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems for testing performed in the subspecialty of Oral Pathology for the years of 2018 through 2019. Findings: 1. The laboratory's manual and quality assurance (QA) records were reviewed: 2. The manual and the QA records reveal the following: *Quarterly, ten (10) surgical pathology cases are selected at random, by accession #. The slides and reports are reviewed for recording, stenographic and diagnostic deficiencies and inaccuracies. *The last documented QA check was performed in 2017. 3. The laboratory failed to follow the established QA process for the oral pathology services provided. 4. On a Recertification survey conducted on 12/11/2019 at 1:15 PM, the LD confirmed the above findings.