

DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

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From: Dr. Gaurav Sharma (Pathology and Laboratory Medicine), on behalf of Dr. Richard Leach (Chair, Women's Health Services) and Dr. Richard Zarbo (Chair, Pathology and Laboratory Medicine).

To: WHS and Pathology Leadership, see Distribution List

Date: 02/03/2022

Re: PPM Testing (including Fern) at L&D | CLIA

MEMORANDUM

Provider Performed Microscopy (or PPM) procedures are a select group of moderately complex microscopy tests commonly performed by health care providers during patient office visits. PPM procedures fall under the Clinical Laboratory Improvement Amendments (CLIA '88) purview, a federal law that covers diagnostic testing done on humans, excluding clinical trials and research. CLIA is enforced by CMS and its accrediting agencies. Individual performing diagnostic testing (including PPM) must meet specific CLIA requirements.

As of 2021, PPM testing at Labor and Delivery (L&D) at certain hospital locations was not on a CLIA certificate. Therefore, there was a need to list the PPM program on a new or existing CLIA certificate. Additionally, in early discussions with Women's Health Services (WHS), there was a desire to initiate the PPM program with a larger cohort of WHS providers.

On 01/26/2022, on behalf of the Pathology and Laboratory Medicine Service Line, Mr. Hayward (Manager, Point of Care Testing) and Dr. Gaurav Sharma (Division Head, Regional Laboratories and Point of Care Testing, Associate Medical Director, Clinical Pathology Core) were invited to present at the WHS Clinical Care Council Meeting. The meeting was organized on Webex and included physician and non-physician WHS leadership from across the System. Dr. John Carey, Vice-Chair of Clinical Pathology, was in attendance. Pathology's presentation included an HFHS-specific slide deck as well as a 15-minute explainer video around CLIA requirements for PPM.

The main question on Pathology's agenda item was a decision on the number of WHS providers that need to perform PPM at L&D of individual hospitals. WHS Clinical Care Council had to make this decision. The choice for WHS Clinical Care Council was between

(a) a Pathology-controlled program with pathologist CLIA directors, with a total cohort of no more than 30 WHS PPM providers/site, or (b) a WHS-controlled program with an obstetrician CLIA directors, with no limit on WHS PPM providers.

After the formal presentation and an open Q&A session that included questions from Drs. Leach, Lee, Goyert, and others- WHS Clinical Care Council opted to choose the option of a Pathology-controlled PPM program with the following attributes:

- PPM Program in the L&D will be listed on the activity menu associated with a CLIA certificate that lists Pathology Service Chiefs as the CLIA director.
- Pathology will bear the responsibility of overseeing the PPM Program. Pathology's CLIA directors will delegate responsibilities to their existing Point of Care Coordinators (POCCs) at these sites. These responsibilities will be in addition to POCCs overseeing other waived and non-waived testing.
- The cost of purchasing new equipment (e.g., microscopes) and maintaining existing equipment, reagents, proficiency testing, reagents, recommended training/competency programs, and other supplies will be with WHS.
- PPM testing cohort will be limited to no more than 30 PPM providers/site. Oversight for over 30 PPM providers/sites will need to be shared by WHS. The additional effort is estimated to be 0.2 FTE for each additional 40 PPM providers.
- Pathology's POCC Technical Team will endeavor to standardize training/competency across different hospitals.
- At each site: Pathology and WHS leadership will coordinate the following:
 - Annually, WHS leadership will provide a list of providers who need to be enrolled at that site's PPM Program. At each site, WHS and Pathology leaders will come to an agreement on when and how this list will be compiled and communicated.
 - Throughout the year, if WHS wants to add new providers to the PPM program or initiate new PPM testing services, it will inform the local POCC and the site CLIA director. No new testing or provider will be initiated in the PPM program without the approval of the site's pathologist CLIA director.
 - Throughout the year, Pathology's POCC will follow up with WHS providers who might be behind on training and competency. However, suppose the WHS provider is unwilling or unable to complete training or competency. In that case, the issue will be referred to the local WHS leadership. In the interim, the pathologist CLIA director reserves the right to discontinue the participation of individual WHS providers.
- Depending on the CLIA certificate, the PPM program may be inspected as part of the biennial inspections. If so, Pathology will be responsible for coordinating these inspections.

Towards the end of the meeting, meeting participants reaffirmed their commitment to collaborate towards the success of the PPM program in L&D. On 01/31/2022, this information was shared with the Pathology service chiefs of all Henry Ford Hospitals. They affirmed their understanding and support. Mr. Hayward will share this information with the individual POCCs across the System. Individual POCCs will continue to coordinate with their local WHS peers and bring the PPM program to full compliance at the earliest.

At this point, please review this memorandum, distribute it to individuals who will be involved with PPM programs, and retain a copy for future reference. If you have any questions, please contact POC Testing Group (pochfh@hfhs.org).

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