Instructions for Specimen Submission for Methylation Profiling

Background: The Laboratory of Pathology, National Cancer Institute, National Institutes of Health (NIH), performs CLIA/CAP certified methylation profiling for tumors of the central nervous system (brain and spine) as a nonpaid expert to disseminate information. Methylation profiling, using the current classifier (published in Capper et.al., Nature 2018. PMID: 29539639), can in many cases help confirm or clarify a diagnosis and/or provide relevant subtyping information for a variety of CNS neoplasms.

It is important to understand that the Laboratory of Pathology does not render opinions or interpretations about a patient's clinical treatment plan or address medico-legal questions. We are not a medical provider to non-NIH patients beyond the purpose of providing a diagnosis. Our focus is solely on the diagnostic considerations regarding the pathology case submitted to us.

Also, please note that review of cases by the Laboratory of Pathology is accepted in support of our mission to serve the public with the dissemination of information to the extent that we are able under our laws, policies and available internal funding. If selected, your submission will be reviewed by neuropathologists who will make every effort to integrate the clinical, histologic, immunohistochemical, and genomic features along with the methylation classifier results into an integrated histo-molecular diagnosis. If you have any further questions, please feel free to contact us.

Before submitting anything to the Laboratory of Pathology, you must assure that you have appropriate, applicable patient and institutional authority and consent to do so. Once received, NIH will protect the information by following applicable federal laws and rules. If the submitted case is found to be challenging and educational, de-identified methylation and clinical data may be selected for presentation at the NIH Tumor Board or Consensus Conference to appropriate medical or research experts to obtain expert opinions regarding diagnostic problems, unusual scientific value in connection with the treatment of patient, or in order to accomplish the purpose of improving the classifier, including research reports.

Information to Submit:

If you wish to have us review your pathology case, please send:

1. This Requisition Form with requestor's contact information so that we know where to send our interpretation
2. Patient/Case information
   a. Please provide diagnostic considerations/specific questions related to pathology interpretations, as well as any molecular information (for example gene mutations/NGS, etc.) that may be available
3. Sample information
4. At least ONE representative tissue block or 10 unstained slides
5. Representative H&E plus Relevant IHC-stained slides (if available),
6. Pathology reports and, if possible, with clinical data specific to the submission.

How to Submit:

Please have all material and accompanying report(s) sent to:

> **Clinical Methylation Laboratory**
> **Laboratory of Pathology, NCI, NIH**
> **Attn: Zied Abdullaev**
> **10 Center Drive, Room 2S235**
> **Bethesda, MD 20892-1500**
> **NIHMethylationProfiling@mail.nih.gov**

Please send all material in the same packet – together. It is important to note that material sent to the NIH Laboratory of Pathology becomes a part of our workload, therefore some representative material may be retained by the pathologist at his or her discretion for use, including research use, unless. material sent to our laboratory is to be returned or sent on to another organization, and if so please request specifically in writing.

* Capper, et al. DNA methylation-based classification of central nervous system tumours. Nature, 555, 469–474(2018)

REQUISITION FOR METHYLATION PROFILING

REQUESTOR INFORMATION

Requestor name:	
Submitting facility:	
Email for Final reports:	
Phone number:	

PATIENT/CASE INFORMATION

Patient Name (last, first, middle):	
Sex:	◯ male ◯ female **DOB:**
Outside Case #:	
Procedure Date:	
Site of the procedure:	
Working Dx / diagnostic considerations:	
NGS/molecular results (if any):	

MATERIALS SUBMITTED

☐ **Tissue block; or**	
☐ **Unstained slides (*10 minimum*):**	
☐ **Pathology report:**	
☐ **HE / IHC stains:**	

CERTIFICATION

- *I certify that I have read the "Instructions for Specimen Submission for Methylation Profiling" and I have authority under applicable law and my institution's policy to provide the information and specimens in accordance with NIH's terms and use.*
- *I certify that I am authorized to transmit and am transmitting this information and material for NIH's future use of the de-identified methylation and clinical data for its future improvement of the classifying algorithm, which includes research purposes and publications.*
- *I also agree that this submission may be presented at the NCI Tumor Board and Consensus Conference.*

Signature: **Date:**