NOTICE OF PRIVACY PRACTICES

Effective Date: September 23, 2013 Revision Date: March 25, 2021 BioReference
LABORATORIES
an OPKO Health Company

THIS NOTICE DESCRIBES HOW MEDICAL AND PERSONAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

Our Commitment to Safeguard Your Protected Health Information.

BioReference Laboratories, Inc. and its subsidiaries and divisions, including but not limited to, GeneDx, Inc., Florida Clinical Laboratory, Inc., and GenPath (collectively "BRLI") are committed to complying with and addressing data privacy requirements under all applicable laws, including but not limited to the Health Insurance Portability and Accountability Act (HIPAA). This notice of privacy practices (NOPP) explains how we handle your protected health information (PHI) in connection with the provision of clinical laboratory testing services.

BRLI is required by law to protect the privacy of health information that may reveal your identity and provide you with a copy of this NOPP, and to follow its terms then in effect. However, BRLI reserves the right to change its privacy practices and the corresponding policies and procedures and, where permitted by applicable law, to make these changes effective regarding PHI created or received prior to the effective date of such changes. Should we make changes to this NOPP, we will post a revised NOPP in our website and in our patient service centers. BRLI may also need to materially change its policies and procedures as necessary to comply with changes in the law and for other valid reasons, in which case BRLI will promptly revise its policies and this NOPP and distribute the revised NOPP in the manner described below.

You have the right to obtain a paper copy of the NOPP upon request. A copy of BRLI's current NOPP will always be available in the reception area of our patient service centers. You will also be able to obtain your own copy by accessing our website at http://www.bioreference.com/privacy calling our office or at the time of your on-site visit

If you have any questions about this NOPP or would like additional information, please contact our Privacy Office at 800- 229-5227 Ext 8222.

Please address any written request (such as requests for a copy of this NOPP, access to your record, to restrict a disclosure to a payer, etc.) to:

Privacy Officer

Privacy Office

BioReference Laboratories, Inc. 481 Edward H. Ross Drive Elmwood Park, NJ, 07407 Fax: (201) 663-6585

EXAMPLES OF PROTECTED HEALTH INFORMATION

Information that we have provided or will provide testing services to you or information about your health, such as a diagnosis, procedures, or information about your healthcare provider in combination with your demographic information (such as name, home or email address, or date of birth); or unique numbers that may identify you (such as your social security number, your phone number, or your driver's license number).

HOW WE MAY USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATIONWe may collect, use, disclose, and maintain your PHI for the following purposes:

For Treatment, Benefits and Services: As a service provider, we may disclose your PHI to doctors, nurses, and other health care providers who are involved in your health care, and they may use such PHI to treat you, While providing services, we may use your PHI to determine care management options. For example, your PHI will be shared among your doctor(s) and healthcare providers. Your doctor may also share your health information with another doctor or healthcare provider to whom you have been referred for further treatment.

We may also make your PHI available to providers by making it accessible through a Health Information Exchange (HIE), an electronic network that makes it possible to share information electronically, but no one will be permitted to access it through the HIE without your consent except in an emergency, unless you direct us not to allow access during an emergency. Be aware that if your physician allows us to transfer your laboratory and pathology reports to his or her electronic health record (EHR) in his or her office, once they have been transferred, anyone taking care of you at that office may be able to access your laboratory and pathology results directly.

For Payment: We may use and disclose your PHI to bill and collect payment for your healthcare and/or release portions of your PHI to a private insurer to get paid for services that we delivered to you. For example, we may share your PHI with your health insurance plan so it will pay for your services or to obtain prior authorization for your services.

For Health Care Operations: We may use and disclose your PHI while operating our clinical laboratory. For example, we may use your PHI for certain administrative, financial, legal, and quality improvement purposes, such as to conduct quality assessments, internal audits, general administrative and business planning activities and other activities necessary to support our healthcare operations. We may share your health information with other health care providers and payors for certain of their health care operations.

if the information is related to a relationship the healthcare provider or payor currently has or previously had with you, and if the healthcare provider or payor is required by federal law to protect the privacy of your health information.

Testing Alternatives and Services. In the course of providing services to you, we may use your health information to contact you with a reminder that you have an appointment for services. We may also use your health information in order to recommend possible alternatives or services that may be of interest to you. However, to the extent a third party provides financial remuneration to us so that we make these treatment-related or health care operations-related communications to you, we will secure your authorization in advance as we would with any other marketing communication (as described later in this NOPP).

Business Associates: We may disclose the minimum amount of your PHI necessary to contractors, agents and other business associates who need the information to help us with billing or other business activities related to the services we provide. For example, we may share PHI with a billing company that helps us obtain payment from your health insurer, an attorney or with a quality assurance consultant to obtain their advice regarding our operations and comply with the law. If we do disclose your PHI to a business associate, we will have a written contract with them that requires the business associate and any of its subcontractors to take reasonable steps to protect the privacy of your PHI as required by law and/or contract.

When Required by Law: We may collect, use, maintain, or disclose your PHI as required by law to do so. For instance, under the United States' *Clinical Laboratory Improvement Amendments* of 1988 (CLIA), we are required to obtain and maintain for designated periods of time personal health data and specimens belonging to patients for whom we are providing laboratory testing services. Therefore, while you may refuse to provide BRLI with your PHI, we are unable to test any specimen of yours without the certain data elements which we are required to obtain under CLIA. Please note that the CLIA-mandated retention periods can range from two (2) years for test requisitions and authorizations to ten (10) years for pathology test reports and histopathology slides. For more information on the specific CLIA-mandated retention periods please check 42 C.F.R. § 493.1105, as amended from time to time. In addition, we maintain patient information in connection with pending litigation, legal processes, legal claims, compliance, regulatory matters, and investigations, as necessary.

For Public Health Activities: We may disclose PHI when we are required to collect information about disease or injury, or to report vital statistics to the public health authority. We are also required to release some PHI about you to your employer if your employer hires us to perform a pre-employment test or we discover that you have a disease that your employer must know about to comply with employment laws.

For Research Purposes: In certain circumstances, pursuant to the approval and supervision of a privacy board, we may use and disclose your PHI to our research staff and their designees to assist in medical research.

Victims of Abuse, Neglect, or Domestic Violence: We may release your PHI to a public health authority that is authorized to receive reports of abuse, neglect, or domestic violence. For example, we may report your PHI to government officials if we reasonably believe that you have been a victim of such abuse, neglect, or domestic violence. We will make every effort to obtain your permission before releasing this information, but in some cases, we may be required or authorized by law to act without your permission.

Judicial and Administrative Proceedings: We may disclose your PHI in response to valid court orders, court-ordered warrants, and judicial summonses and subpoenas, grand jury subpoenas, and administrative requests. We may also disclose your PHI in response to a discovery requests or other legal process and legal requests, but only if efforts have been made, either by the requesting party or us, to first tell you about the request or to obtain an order protecting the information requested.

For Health Oversight Activities: We may disclose PHI to an agency responsible for monitoring the health care system for such purposes as reporting or investigation of unusual incidents and inspecting our facility. These government agencies monitor government benefit programs such as Medicare and Medicaid, as well as compliance with government regulatory programs and civil rights laws.

To Avert Threat to Health or Safety: To avoid a serious threat to health or safety, we may disclose PHI as necessary to law enforcement or other persons who can reasonably prevent or lessen the threat of harm.

For Specific Government Functions: We may disclose PHI of U.S. military personnel and veterans and to correctional facilities in certain situations, to government benefit programs relating to eligibility and enrollment, and for national security and intelligence activities, such as protection of the President.

For Law Enforcement: We may disclose your PHI to comply with court orders, to assist law enforcement officers with identifying or locating a suspect, fugitive, witness, or missing person; if we suspect that death resulted from criminal conduct; or if necessary to report a crime that occurred in any of our facilities;

Workers' Compensation: We may disclose your PHI for workers' compensation or similar programs that provide benefits for work-related injuries, as authorized by and to the extent necessary to comply with laws regarding workers' compensation or similar programs providing benefits for work-related injuries or illness.

Coroners, Medical Examiners and Funeral Directors: Where allowed by applicable law, we may disclose PHI relating to an individual's death to coroners, medical examiners, or funeral directors, and to organ procurement organizations relating to organ, eye, or tissue donations or transplants. Note: Information belonging to patients who are deceased more than 50 years is **not** considered PHI.

To Family, Friends, or Others Involved in Your Care: If you do not object, we may share your PHI with your family members, friends, and others if this information is directly related to their involvement in your care, or payment for your care. In some cases, we may need to share your information with a disaster relief organization that will help us notify these persons.

Completely De-identified or Partially De-identified Information: We may use and disclose your health information if we have removed any information that could identify you. Where permitted by applicable law, we may also use and disclose health information about you for research, public health, and specific healthcare operations if most of your identifiers are removed and the person who will receive the information signs an agreement to protect the privacy of the information as required by federal and applicable state law. In that case any direct identifiers (such as your name, street address, social security number, phone number, fax number, home address, or license number). would be removed, but your zip code, date of birth, or dates of service would not be removed.

For Internal Assessments and Healthcare Operations Communications: We may use your PHI to help us understand which products, services and offers are relevant to you, to improve our products and services, and generally to communicate news or matters involving quality of care that may be relevant to you. Keep in mind that this use is solely for internal purposes and that we will not sell any of your PHI to any third party. If you do not wish to receive these communications, you can inform us of your decision by providing notice to the Privacy Office at the address set forth in this NOPP and we will not engage in such activity.

Other Permitted Disclosures: We will use your PHI, only for the purposes for which we collect it, unless we reasonably consider that we need to use it for another reason that is compatible with the original purpose. If we need to use your PHI for another purpose, we will explain the legal basis we rely on. Our legal basis to use, and disclose PHI includes (i) your consent (which may subsequently be withdrawn at any time by contacting the Privacy Office at the address listed in this NOPP), (ii) legitimate business needs, which include but are not limited to ensuring that we provide accurate results and that we have the right information on file to communicate with you at any time, obtaining payment for our services, and ensuring that we comply with our quality assurance policies, (iii) creation or performance of contractual obligations (e.g. communicating laboratory results to you or your provider), and (iv) compliance with legal requirements (e.g. complying with a court order or a legal mandate).

Requirement for Written Authorization: We will only make other uses and disclosures of your PHI that are not described in this NOPP, and not otherwise required or allowed by law, with your written authorization. For example, we will not sell your PHI or use or disclose your PHI for marketing purposes without your written authorization.

If you provide us with written authorization, you may revoke that written authorization at any time, except to the extent that we have already collected, maintained, used, or disclosed the same in accordance with the provisions set forth above. You must revoke your authorization in writing by contacting the Privacy Office at the address listed in this

Additional Protections for HIV, Alcohol and Substance Use, Mental Health, and Genetic Information: We apply additional protections to PHI that is subject to other state and federal laws, including information and programs relating to HIV/AIDS, alcohol and substance use, mental health, and genetic testing and treatment. Special privacy protections applying to PHI relating to alcohol and substance use, mental health information, and genetic information and HIV/AIDS -related information. Subject to limited federal and state legal requirements and the above uses and disclosures, we will obtain your permission prior to disclosing HIV/AIDS-related information, alcohol and substance use, mental health, and genetic related information.

Right To Notice of Breach of Unsecured Health Information: We are required by law to maintain the privacy of your PHI, to provide you with this NOPP containing our legal duties and privacy practices with respect to your health information, and to abide by the terms of this NOPP. It is our policy to safeguard your health information so as to protect the information from those who should not have access to it. If, however, for some reason we experience a breach of your unsecured protected health information, we will notify you of the breach as required by applicable law.

APPLICATION

The privacy practices described in this NOPP apply to BioReference Laboratories, Inc. and all of its subsidiaries, divisions, including but not limited to, GeneDx, Inc., Florida Clinical Laboratory, Inc., and GenPath.

DATA SECURITY

We maintain reasonable security measures to safeguard your PHI from loss, interference, misuse, unauthorized access, disclosure, alteration, or destruction. We also maintain reasonable procedures to help ensure that such data is reliable for its intended use and is accurate, complete, and current.

USE OF COOKIES

From time to time we use cookies and similar technology in our websites and e-mail communications for legitimate business purposes such as collecting statistics, helping optimize site functionality and security, to determine the effectiveness of our communications with customers and, generally, to help us better understand how we can improve our services. Cookies are small files that are placed on your computer by websites that you visit or certain emails you open. These include "preference cookies," "security cookies," or "process cookies." Cookies are widely used in electronic communications around the world. Upon accessing our website, you provided us with your consent to the placement of cookies in your computer.

YOUR RIGHTS TO ACCESS AND CONTROL YOUR PHI

To Request Restrictions on Uses/Disclosures: You have the right to ask that we limit how we use or disclose your PHI. We will consider your request but are not legally bound to agree to the restriction. To this effect, you will need to contact our Privacy Office at the address listed in this NOPP and provide us with your written instructions, which we will keep on file. To the extent that we do agree to any restrictions on our use/disclosure of your PHI, we will put the agreement in writing and abide by it to the extent permitted by law or the information is needed to provide you with emergency treatment. Once we have agreed to a restriction, you have the right to revoke the restriction at any time. Under some circumstances, we will also have the right to revoke the restriction as long as we notify you before doing so; in other cases, we will need your permission before we can revoke the restriction. We are required, however, to honor your written request if you direct us not to share specific PHI with your insurance company relating to a service you or someone on your behalf has paid for out-of-pocket and in full. It is your responsibility to inform other providers who may receive copies of such information that they may not share this information with your insurer.

To Choose How We Contact You: You have the right to ask that we send you information at an alternative address or by an alternative means. We must agree to your request as long as it is reasonably easy for us to do so and we may not ask the reason for the request.

To Inspect and Copy Your PHI: You have the right to inspect and obtain a copy of any of your PHI in either electronic or paper form for as long as we maintain this information in our records. We will provide the records in the specific form and format that you request if it is readily producible in such form or format. To obtain a copy of your PHI, please submit your request in writing. Depending upon where you live, we may charge a fee as permitted by law for the costs of copying, mailing or other supplies necessary to fulfill your request. We generally require payment before or at the time we provide the copies and will let you know the amount due in advance.

Under certain very limited circumstances, we may deny your request to inspect or obtain a copy of your information. If we do, we will provide a written statement that explains the reasons for the denial and a description of your right to have that decision reviewed. In such cases where you have the right to have your denial reviewed, we will describe the review process to you in writing. If your request for access to your PHI is denied for any reason, we will describe to you in writing how you can file a complaint with BRLI or with the Secretary of the United States Department of Health and Human Services' Office of Civil Rights (OCR).

To Request Amendment of Your PHI: If you believe that the PHI in our system is incorrect or incomplete, you may ask us to amend the information for as long as the information is kept in our records. If you wish to amend your PHI, please request an amendment in writing including why you think we should make the amendment. Ordinarily we will respond to your request within 60 days. If we need additional time to respond, we will notify you in writing within 60 days to explain the reason for the delay and when you can expect to have a final answer to your request. If we deny part or all of your request, we will provide you with a written notice explaining our reasons for doing so and how you can appeal the decision. You will have the right to have certain information related to your requested amendment included in your records. For example, if you disagree with our decision, you will have an opportunity to submit a statement explaining your disagreement which we will include in your records. We will also provide you with information on how to file a complaint with us or with the Secretary of the Department of Health and Human Services.

To Receive an Accounting of Disclosures: You have a right to submit a request in writing asking for information about our disclosures of your PHI, except for disclosures made:

- For treatment, payment, and operations;
- To you or your personal representative;
- At your written request;
- For national security purposes;
- To family, friends, and other persons involved in your care;
- To correctional institutions or law enforcement officers;
- Incidental to permissible uses and disclosures of your PHI (for example, when information is overheard by another person passing by);
- For research or public health using limited portions of your health information that do not directly identify you; and
- That occurred prior to the compliance date of this requirement.
 The scope of your right to request an accounting may be modified from time to time to

comply with changes in federal law or state law.

Ordinarily we will respond to your request for an accounting within 60 days. If we need additional time to prepare the accounting you have requested, we will notify you in writing about the reason for the delay and the date when you can expect to receive the accounting. In rare cases, we may have to delay providing you with the accounting without notifying you because a law enforcement official or government agency has asked us to do so.

How to Complain About Our Privacy Practices: If you believe your privacy rights have been violated, you may file a complaint with BRLI or the federal agency that enforces HIPAA by submitting your complaint as described below:

Privacy Officer
HIPAA Privacy Office
BioReference Laboratories, Inc.
481 Edward H. Ross Dr. Elmwood Park, N. J. 07407
T: 800 229-5227 Ext. 8222

www.hhs.gov/ocr/hipaa

Office of Civil Rights
U.S. Department of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201
Telephone: (800) 368-1019

You will not be penalized or subject to retaliation for filing a complaint