Dear Valued Client:

Thank you for allowing BioReference Health, LLC ("BioReference®") to serve your patients' laboratory testing healthcare needs. We are dedicated to providing you and your patients with the highest quality service. We are equally committed to complying with all applicable federal and state healthcare laws, rules, and regulations. This includes guidance published by the United States Department of Health and Human Services Office of Inspector General (the "OIG") available at Compliance Program Guidance for Third-Party Medical Billing Companies (hhs.gov). The OIG published an updated General Compliance Program Guidance, which is available at HHS-OIG General Compliance Program Guidance | November 2023.

The OIG recommends that clinical laboratories send annual notices to health care providers who use their services, informing them of the laboratory's test ordering and billing policies and providing relevant information about the laws, rules, and regulations governing laboratory services. This Annual Notification is being issued in accordance with that recommendation.

KEY HEALTHCARE LAWS: **Fraud & Abuse Laws | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services (hhs.gov)**

PHYSICIAN SELF-REFERRAL (STARK II) [42 CFR 411.355]
The Stark Law, also referred to as the physician self-referral law, prohibits healthcare providers from referring patients to a laboratory in which they have a financial interest. It serves as both a referral and a billing regulation. The law applies exclusively to Medicare patients seeking designated health services, such as laboratory testing.

ANTI-KICKBACK [Section 1128B (b) of the Social Security Act]
While the self-referral law must involve physicians, anti-kickback regulations apply to anyone who "knowingly and willfully offers, pays, solicits, or receives remuneration to induce business reimbursed under the Medicare or Medicaid programs."

CIVIL MONETARY PENALTIES LAW [42 US Code§ 1320a-7a]
The Civil Monetary Penalties Law allows the Department of Health and Human Services to impose a civil monetary penalty, an exclusion from a program, or an evaluation of a physician who has engaged in abusive or fraudulent behaviors. It protects the Government from being overcharged. It is illegal to submit claims for payment to Medicare or Medicaid that are known to be false or fraudulent. Filing false claims may result in fines of up to three times the program's loss, plus $11,000 per claim filed.

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TEST ORDERING POLICIES:

The 4Kscore® Test: The 4Kscore Test is a blood biomarker test for assessing the presence of aggressive prostate cancer. Formerly a Laboratory Developed Test (LDT), the 4Kscore Test was approved by the FDA on December 9, 2021. Payer coverage policies require a legible signature from the physician and documentation of shared decision-making (SDM) concerning the 4Kscore between the ordering provider and patient must be present in the medical record, and a copy of the same shall be provided to the performing laboratory prior to the test being performed. For health care providers, a legible signature includes a printed name along with authorized provider credentials, an inked or compliant electronic signature, and the date. **Stamped health care provider signatures are not acceptable and will not be accepted.**

Signed Test Requisitions: Federal, state, and commercial payers continue to increase review efforts to verify that the ordering health care provider has signed the test requisitions for laboratory tests ordered. The requisition needs to be signed and dated; the order can be electronically signed through an electronic medical record or ordering system; or documentation needs to be in the patient's medical record at the treating provider site indicating intent to order the Test(s) and signed by the authorized ordering provider. When relying on medical record documentation to support the intention to order, the record must accurately describe the individual Test(s) to be performed by the laboratory. If submitting a paper requisition, we ask that you sign the hard copy requisition when ordering any testing submitted to our laboratory. Payer guidance refers to industry best practices for a complete requisition or order, as one signed by the physician, and includes NPI, professional credentials, and date of order. A valid electronic signature will include a printed statement such as “electronically signed by,” or “electronically authenticated by,” followed by the practitioner's name and professional credentials, date, and time stamp. System safeguards should be in place to avoid unauthorized access and use of the electronic signature by anyone other than the designated individual. The system should protect record integrity and prevent unapproved alteration of the electronic signature. A completed, signed requisition or order will mitigate the risk of BioReference reaching out to your staff to retrieve evidence of the signed test order in your patient’s chart. **Stamped health care provider signatures are not acceptable and will not be accepted.**

Pre-Authorization for Laboratory Testing: Commercial health insurance payers are increasing oversight and limiting access by requiring pre-authorization for certain laboratory tests, including but not limited to specific genetic carrier biomarkers and infectious disease panels. When the laboratory submits pre-authorization requests on behalf of the patient or physician, supporting medical documentation may be required and therefore should be provided at the time of the test order. Any pre-authorization paperwork must accompany the laboratory test requisition and specimen from the ordering provider.

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If pre-authorization is obtained prior to specimen collection, please include the pre-authorization number on the test requisition. Failure to provide this at the time of the test order may result in delays in your patient's testing.

Medicare ABN: An ABN ("Advance Beneficiary Notice") is a written notice provided to Medicare beneficiaries when a healthcare provider believes that a service or item may not be covered by Medicare based on medical necessity or frequency limitations. The notice informs the patient that they may be personally responsible for the cost of the service if Medicare denies coverage. The ABN must clearly explain the reason for the potential non-coverage, and the patient must sign the form prior to specimen collection to acknowledge they understand they could be billed. This allows the patient to make an informed decision about whether to proceed with the laboratory testing.

For the laboratory to bill the patient, Medicare (and other payers) require that a patient sign an ABN informing them of the non-covered status of a test before the Test is performed. Since we do not interact directly with patients, it is the responsibility of the ordering provider to be familiar with applicable National Coverage Determination ("NCD") and Local Coverage Determination ("LCD") rules, including ABN requirements, to ensure that informed medical necessity determinations, which take into consideration a patient's financial ability, are made for each patient and are supported by a signed test order in the patient's medical record. The ABN must be signed prior to specimen collection and must be attached to the laboratory test order and submitted along with the specimen. Link: www.medicare.gov

Infectious Disease Testing: BioReference ***cannot accept*** Category A infectious substances as defined by IATA (Dangerous Goods Regulations BioReference Laboratories, Inc. 3.6.2.1.1 Definition - Infectious Substances), which include, but are not limited to, specimens that may harbor variant Creutzfeldt-Jakob Disease (mad cow disease), or tissue cultures of Mycobacterium tuberculosis. FFPE, fresh blood or bone marrow specimens, and body fluids are acceptable from patients with known tuberculosis.

Tuberculosis cases must be cultured within 24 hours, and BioReference does not have the capability to culture for tuberculosis. Specimens from other patients received in the same package will be considered potentially contaminated and handled similarly, regardless of origination. If no options are available, specimens will be disposed of as biohazardous waste after client notification. Please refer to IATA Dangerous Goods Regulations for a complete list of Category A Infectious Specimens: https://www.iata.org/whatwedo/cargo/ dgr /Documents/infectious-substance- classification-DGR56-en.pdf

Radioactive Specimens: BioReference ***does not accept*** radioactive pathology samples, such as a prostate with radioactive seeds. Specific shipping IAEA Shipping Standards must be followed when sending to a qualified testing laboratory.

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Non-BioReference Requisition, Incomplete BioReference Requisition, or Handwritten Test Order: Processing of your test order may be delayed if BioReference receives a test order on a non-BioReference test requisition form, an incomplete BioReference test requisition form or a handwritten test order.

Just a reminder that it is BioReference policy for any handwritten test order received for a **"CBC"**, BioReference shall perform a **"CBC w/DIFF, Platelet Ct."** due to the stability of the specimen and/or medical necessity requirements BioReference Test Requisitions include both test codes **0053-9 CBC w/DIFF, Platelet Ct**. and **0034-9 CBC w/o DIFF (Hemogram)/Platelet Ct**. In addition, both test codes (0053-9 and 0034-9) are available in InsightDx.

Provision of Equipment and Supplies: In accordance with applicable law, it is BioReference policy to prohibit the provision of Equipment or Supplies to Healthcare Providers ("HCPs") which may have an independent value to the HCP or which could be used for multiple purposes by the HCP as that may be viewed as an inducement under the Stark Law, Anti-Kickback Statute and comparable state fraud and abuse laws. Exceptionally, and absent a specific state law prohibition, BioReference may make available certain Equipment and Supplies to HCPs if there is a Legitimate Operational and Quality Need and that any Equipment or Supplies so provided are integral to and used by the HCP exclusively for ordering testing performed by BioReference. BioReference will distribute supplies to clients as needed and based upon client utilization of testing performed by BioReference.

***STANDARDIZED POLICIES*:**

Coverage Standards: As you know, Medicare, Medicaid, and some Private / Commercial Payers only cover laboratory tests that are reasonable and necessary for the treatment or diagnosis of a patient. Each Provider is responsible for ordering tests that are reasonable and necessary for each patient and that the ordering provider intends to use in the patient's treatment and care. Medicare and its contractors have developed National and Local Coverage Determinations ("NCDs" and "LCDs") that provide guidelines regarding Medicare coverage of specific laboratory tests. These policies identify the conditions for which the included tests are or are not covered or reimbursed by Medicare, typically referring to specific ICD-10 codes deemed to support coverage. You can find NCDs and LCDs online. Medicare reimbursement for each laboratory test can be found in the Medicare Clinical Laboratory Fee Schedule and the Medicare Physician Fee Schedule.

Where an A.M.A. CPT-defined Organ or Disease-Oriented Panel is ordered, that panel will be paid for only if all panel components are medically necessary.

It is the policy of BioReference to only bill for panels and profiles when all the component tests are medically necessary, the ordering health care provider agrees only to order panels or profiles when all component tests are medically necessary for the patient on the date of service. Please find the American

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Medical Association (AMA.) CPT-defined Organ or Disease-Oriented Panels: R3619CP (cms.gov) https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r3619cp.pdf

Laboratory Test Ordering Options: Regulations require that the performing laboratory have a written or electronic test request for patient laboratory testing from an authorized person to order testing as defined by state law per the Clinical Laboratory Improvement Amendments ("CLIA"). The BioReference test requisition forms are designed to emphasize ordering provider choice and encourage ordering providers to order only those tests the ordering provider believes are appropriate and medically necessary for the diagnosis or treatment of each patient. If BioReference receives a test order on a non-BioReference test requisition form or an incomplete BioReference test requisition form, processing your test order may be delayed.

BioReference has three (3) options available by which an authorized healthcare provider may order BioReference testing. They include: 1) manual paper test requisitions, 2) online test ordering via our proprietary electronic ordering system lnsightDx, and 3) an EMR interface. Online ordering and EMR interface ordering are the more efficient methods of test ordering and help reduce potential human errors in the order creation and entry process. BioReference accepts handwritten test requisitions, but they must be legible, unambiguous, complete, and clear. Incomplete, unclear or inaccurate test requisitions may delay the processing of a test order. The laboratory will not accept generic standing orders for tests frequently ordered by your office. All orders must be patient-specific.

Verbal Test Orders: If an authorized healthcare provider orders a test by telephone or wishes to add a test to an existing order, the laboratory must solicit a written or electronic authorization within thirty (30) days of the verbal request. If BioReference receives an oral ruling, we will fax or email a confirmation. Change in Test Authorization Form detailing the said order to the authorized healthcare provider and request that the authorized healthcare provider sign and send the test order form to BioReference.

Billing Information: BioReference test requisitions allow space to denote all information required for our Billing Department to submit clean claims to Medicare, Medicaid, and all Commercial, Federal, and State-Funded insurance payers. The following information is necessary with any request for testing. Failure to provide the required information may result in BioReference contacting the health care provider's office via telephone, fax, or HIPAA secure email to obtain the missing billing information.

- Patient's full, legal name as listed on their current health insurance policy
- Patient's mailing address, including city, state, and zip code
- Patient's date of birth
- Patient's biological gender at birth
- Patient's insurance company name, complete ID or policy number, and complete group number, if

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applicable (if possible, a copy of the front and back of the patient's insurance card should be sent along with the test requisition)

- Ordering Provider or referring physician's name and NPI number (must be authorized Ordering Provider with BioReference.)
- ICD-10 diagnosis code(s) to the highest level of specificity for each Test ordered. ICD-10 diagnosis code(s) must be documented in the patient's medical record
- If using BioReference manual paper test requisitions, the signature of the ordering provider, including the provider credentials
- Submission of test order by electronic means must include a valid electronic signature of the ordering provider, including provider credentials and system time/date stamp

Failure to provide a complete, transparent, and accurate test requisition may delay the processing of a test order. BioReference will not bill Government or private payers for tests and services that are not medically reasonable and necessary, therefore the ordering provider agrees only to order medically necessary tests. Medicare, Medicaid, and commercial payers periodically audit BioReference, and it may be necessary to contact the ordering provider to obtain medical records that support the tests ordered and the claim submitted by BioReference to the payer. BioReference encourages you to promptly comply with payer requests for supporting patient medical documentation.

Authorized Test Ordering: Federal regulations require that a laboratory can only bill Medicare and Medicaid for testing ordered by a licensed physician or other qualified health professional ("QHP") authorized by state law to order laboratory tests. As defined by CLIA "Authorized person" means an individual authorized under State law to order tests or receive test results, or both.

Provider Exclusion and Debarment Verification and Monitoring: BioReference and its affiliates frequently represent and warrants that the Company does not accept any tests ordered directly by or under the supervision of a health care provider who is excluded or debarred regardless of the account bill type or if the state of the exclusion/sanction is not the same as the ordering state. It is the Provider's responsibility to remedy the exclusion with the agency of record. We cannot accept orders from that excluded or debarred Provider unless and until the Provider is removed from the excluded or debarred list. If a provider is excluded, we immediately deactivate their ordering privileges while notifying the account sales representative. Our laboratory regularly screens all providers at account set-up and monthly thereafter against Federal and State exclusion databases.

You represent and warrant that neither you nor any employee, contractor, or agent performing services on behalf of you has been excluded, debarred, suspended, proposed for debarment, or otherwise declared ineligible from any federal or state health care program or federal procurement or non-procurement program or convicted of a criminal offense that falls within the scope of 42 USC§ 1320a-7a. You further covenant that you will disclose any such debarment, suspension, exclusion, proposed debarment, or ineligibility to BioReference immediately upon discovery. Additionally, you

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must notify our laboratory immediately if your license has been revoked or suspended.

PECOS: The Patient Protection and Affordable Care Act requires that physicians and eligible healthcare providers enroll in the Center for Medicare and Medicaid Services to order and refer services, including clinical laboratory tests, for Medicare beneficiaries. Medicare will not pay for clinical laboratory services unless the ordering physician or non-physician practitioner is enrolled in Medicare's Provider Enrollment, Chain, and Ownership System ("PECOS").

If you decide not to bill Medicare for *your* services, you can opt out of Medicare or enroll solely to order and certify. When you opt-out and register as an ordering and certifying Provider, Medicare coverage will apply for Clinical Laboratory Services. BioReference cannot bill Medicare for services ordered and performed for Medicare beneficiaries if the health care provider is not enrolled in PECOS or enrolled but Opted Out. Additional information can be found at https://pecos.cms.hhs.gov/providers/index.html.

Panels/Profiles: BioReference allows you to create a custom panel or profile. Each ordering provider determines whether each Test in a custom panel or profile is appropriate for a given patient. As the ordering provider, you are in the best position concerning the tests you order for each patient. You may order tests individually or modify your custom panel(s) or profile(s) by adding or removing components appropriate for any given patient using the test requisition form. You may modify your custom panel(s) or profile(s), if any, at any time by contacting the Customer Service Department at 800-229-5227 or your Account Executive. **Note: All profiles and panels are subject to medical quality review** and oversight and require approval before ordering by **BioReference.** It is the policy of BioReference to only bill for panels and profiles when all the component tests are medically necessary, so the ordering provider agrees only to order panels or profiles when all component tests are medically necessary.

Diagnosis: Ordering providers solely determine which tests are reasonable and medically necessary for their patients. BioReference solely relies on providers to make that determination and expects providers to submit accurate diagnostic information on their test requisitions. BioReference can provide a list of commonly used ICD-10 diagnosis codes but cannot recommend or suggest specific diagnosis codes to be used. Each ordering provider should document each patient's diagnosis in the patient's medical record and, by order of Section 4317 of the Balanced Budget Act of 1997, should include this diagnosis on any test requisition form submitted to BioReference using the correct ICD-10 diagnosis code(s) to the highest level of specificity.

BioReference may contact health care providers by telephone, fax or email if the required diagnostic information has not been provided. In accordance with Medicare requirements, the ordering provider who requests the laboratory test(s) must maintain documentation supporting medical necessity in the

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beneficiary's medical record for the laboratory test(s) ordered. BioReference will not bill the Government or private payer for tests and services that are not medically reasonable and necessary, so the ordering provider agrees only to order medically necessary tests.

The OIG assumes that an ordering provider who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed, may be subject to civil penalties under the False Claims Act.

Ordering of Discretionary Tests: The billing to a federally funded health care program, such as Medicare or Medicaid, of a test that is not reasonable and necessary for the diagnosis or treatment of a federal health care program beneficiary may be considered to be the submission of a false claim under the federal False Claims Act. If you determine that a test for a Medicare beneficiary is not reasonable and necessary, you must inform the beneficiary that Medicare will not pay for the Test and follow the Medicare ABN section above. The OIG has warned that physicians or other individuals authorized by law to order laboratory tests are subject to sanctions and other remedies under criminal, civil, and administrative law if they knowingly cause the submission of a false claim to any federally funded health care program.

Compliance: BioReference is committed to compliance. Our Code of Conduct and Business Ethics identifies the values and obligations that all BioReference employees, officers, directors, consultants, and sales force must follow https://www.bioreference.com/about/code-of-ethics/. A full copy of our Code of Conduct and Business Ethics is available by written request directed to the BioReference Compliance Department at 481 Edward H. Ross Drive Elmwood Park, NJ 07407.

For any compliance-related questions or concerns, please contact the Compliance Department by phone at 800-229-7902 or via email at ComplianceDepartment@bioreference.com. You can also report compliance issues anonymously through the BioReference compliance hotline at 1-844-783-5587 or by visiting www.lighthouse-services.com/OPKO.

Please be reminded that federal law prohibits offering or paying any form of remuneration, i.e., anything of value, to induce the referral of tests covered by Medicare, Medicaid, or any other federal health care program. Any form of kickback, payment, or other remuneration intended to secure the referral of federal health care program testing business to BioReference is strictly prohibited and it should be reported as outlined above.

Patient Privacy (HIPAA): Under the Health Insurance Portability and Accountability Act (HIPAA), BioReference is a healthcare provider and a covered entity. It is our policy to comply with the letter and intent of the HIPAA privacy and security standards. Our privacy policy is available at https://www.bioreference.com/privacy/

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Clinical Laboratory Consultant: The laboratory's technical staff and Laboratory Director are available to discuss appropriate testing and test ordering. If you have any questions, please do not hesitate to contact Customer Services at (800) 229-5227 Option 1 for assistance.

Please review this information with your staff as appropriate. We value your business and appreciate the opportunity to serve your laboratory needs in conjunction with these initiatives.

Best regards,

Laura Dagney
Laura Dagney
VP, Chief Compliance and Privacy Officer
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References

- NCDs that apply to clinical laboratory testing https://www.cms.gov/medicare-coverage-database/search.aspx
- The Medicare Clinical Laboratory Fee Schedule https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/files
- The Medicare Physician Fee Schedule https://www.cms.gov/medicare/physician-fee-schedule/search/overview

BioReference Health, LLC submits Medicare claims to the following MACs. The complete list of LCDs can be found:

- C.G.S. Medicare (O.H.) https://cgsmedicare.com/
- FCSO (FL) https://tools.fcsomedicare.com/apps/lcd
- NGS (NY) https://www.ngsmedicare.com/web/ngs/medical-policies?lob=96664&state=97133&rgion=93623
- Noridian (CA) https://med.noridianmedicare.com/web/jeb
- Novitas: NJ, MD, DC, PA https://www.novitas-solutions.com/webcenter/portal/MedicareJL/LcdSearch
- Novitas: TX https://www.novitas-solutions.com/webcenter/portal/MedicareJH/LcdSearch