Dear Valued Client:

Thank you for allowing BioReference Health, LLC ("BioReference®") to serve your patients' 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). Recently 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 notices to ordering health care providers who use their services at least once a year to inform the health care providers of the laboratory's policies for test ordering and billing and provide certain other information regarding the laws, rules, and regulations governing laboratory services. This Annual Notice is provided according to 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 known as the physician self-referral law, prohibits healthcare providers from making referrals to a laboratory in which the Provider may have a financial interest. It is a referral rule and a billing rule. The law only applies to Medicare patients seeking designated health services (ex: 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.

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 both the physician and patient when ordering this Test. For health care providers, a legible signature includes a printed name along with authorized provider credentials, either an inked or a compliant electronic signature and the date. For patients, a legible signature includes a printed name and either 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 ordering provider, e.g., MD. 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 practice for a complete requisition or order as one signed by the physician and includes NPI, professional credentials, and date of order. 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 chart. **Stamped health care provider signatures are not acceptable and will not be accepted.**

Pre-Authorization for Laboratory Testing: Insurance payers continue to increase oversight and restrict access by requiring pre-authorization for specific laboratory testing, including but not limited to certain types of genetic carrier biomarkers and infectious disease panels. **When the laboratory submits requests for PA on behalf of the patient/physician, supporting medical documentation may be required and should be provided at the time of order.** Any pre-authorization paperwork ***must accompany*** the laboratory requisition and specimen from the ordering provider. Please include the pre- authorization number on the test requisition. If we do not receive this at the time of the test order, it may delay your patient's testing.

Medicare ABN: If a 'non-covered' diagnosis is used, the patient must be notified before specimen collection and allowed to sign the Advance Beneficiary Notice (ABN). The ABN must be completed for any Medicare patient with suspected claim denial based on medical necessity or frequency limitations. The signed, original ABN must be attached to the laboratory order before submission. 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 NCD and LCD coverage 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 order in the patient's medical record.
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), variant Creutzfeldt-Jakob Disease, or tissue cultures of Mycobacterium tuberculosis. FFPE, fresh blood or bone marrow specimens, and body fluids are acceptable from patients with known tuberculosis. FYI: TB cases must be cultured within 24 hours, and BioReference does not have culturing capabilities for TB. 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.

Non-BioReference Requisition/Incomplete BioReference Requisition/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 also available in InSightDx for your ease of ordering.

Provision of Equipment and Supplies: In accordance with applicable law, BioReference policy prohibits 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 as long as there are 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, so 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 Medical Association (AMA.) CPT-defined Organ or Disease-Oriented Panels: R3619CP (cms.gov)

Laboratory Test Ordering Options: Regulations require that the performing laboratory have a written or electronic 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-BR 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. Our laboratory accepts handwritten test requisitions but needs them to be legible, complete, and straightforward. Failure to provide a comprehensive, transparent, and accurate test requisition may delay the processing of a test order. The laboratory will not accept a generic standing order for tests frequently ordered by your office. All orders must be patient-specific.

Verbal Test Orders: If an authorized person 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 form detailing the said order to the ordering healthcare provider and request that the Provider sign and send the order form to BioReference.

Billing Information: BioReference test requisitions allow space to denote all information required for our Billing Department to submit 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 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 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

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, so the ordering provider agrees only to order medically necessary tests. Medicare, Medicaid, and Commercial Payers audit BioReference from time to time, and it may be required to contact the ordering provider to obtain medical records to support the Test(s)

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 after that 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. You 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. Contacting your Account Executive may also modify your custom panel(s) or profile(s). **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 provide 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 who do not provide the required diagnosis information via telephone, fax, or email. Per Medicare requirements, the physician or qualified NPP who orders the laboratory tests must maintain documentation of medical necessity in the beneficiary's medical record for the laboratory testing 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. Suppose you determine that a test for a Medicare beneficiary is not reasonable and necessary. In that case, you must inform the beneficiary that Medicare will not pay for the Test (see Medicare ABN). 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

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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 or call our anonymous Compliance Hotline at 1-844-783-5587 or email at ComplianceDepartment@bioreference.com. Please call or write if you have any questions or concerns about compliance. Please also remember that federal law prohibits any person from offering or paying any remuneration, *i.e.*, anything of value, to induce the referral of tests that Medicare, Medicaid, or any other federal health care program cover. 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. It should be reported to the anonymous BioReference compliance hotline referenced 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/

Clinical 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

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References

1. NCDs that apply to clinical laboratory testing https://www.cms.gov/medicare-coverage-database/search.aspx
2. The Medicare Clinical Laboratory Fee Schedule https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/files
3. 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