MEMORANDUM OF UNDERSTANDING

Between County of Sonoma and

County of Mendocino

This Memorandum of Understanding (hereinafter "MOU"), dated as of ________, 2024 (hereinafter "Effective Date"), is by and between the County of Sonoma (hereinafter "Sonoma") and County of Mendocino (hereinafter "Mendocino").

1. Recitals

WHEREAS, Sonoma operates its Public Health Laboratory (hereinafter "SCPHL") under the supervision of a Laboratory Director (hereinafter "SCPHL Director"), qualified under the Clinical Laboratory Improvement Act of 1988 (hereinafter "CLIA") to act as a public health laboratory director, and Sonoma is willing to provide certain laboratory services to Mendocino as specified herein;

WHEREAS, Mendocino is in need of the services of a Public Health Laboratory;

WHEREAS, in the judgment of the parties, it is necessary and desirable for Sonoma to provide, and Mendocino to use the services of SCPHL; and

WHEREAS, each party affirms its intent to comply with all applicable laws, including but not limited to CLIA and the Health Insurance Portability and Accountability Act (hereinafter "HIPAA"). With respect to HIPAA, each party represents to the other that it is either a covered entity or a covered component of a hybrid entity.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual covenants contained herein, the parties hereto agree as follows:

2. Sonoma Roles and Responsibilities

Sonoma agrees to provide public health laboratory services for Mendocino. Included and excluded SCPHL services are presented in the attached Exhibit A (Scope of Work), made a part of this MOU by reference.

Sonoma's Department of Health Services ("DHS") shall operate its SCPHL under the supervision of the SCPHL Director, who is qualified under CLIA to act as a public health laboratory director.

Sonoma shall maintain its compliance with the minimum requirements of a public health laboratory according to California Code of Regulations, Title 17, Section 1078, and shall take part in any procedures deemed necessary by the State Department of Health during the term of this MOU.

Sonoma shall perform all testing in accordance with methods approved by the following agencies:

State of California, Health and Human Services Agency, Department of Public Health, Laboratory Field Services, State of California approved Public Health Laboratory # 1361

Department of Health and Human Services, Centers for Medicare and Medicaid Services, Health Care Financing Administration, Clinical Laboratory Improvement Amendments (CLIA), CLIA ID#: 05D0644064

State of California, Environmental Laboratory Accreditation Program Branch Department of Health and Human Services Agency, Environmental Laboratory Certification (ELAP), Certificate #1736

Sonoma shall maintain CDC LRN-B Capacity. As an active member of the Center for Disease Control Laboratory Response Network – Biological (CDC LRN-B), SCPHL is designated as a level-B reference laboratory. As such, SCPHL maintains competency for LRN-B testing methods by having the ability to test for select agents/samples types/tests listed in the high-risk, environmental-sample testing algorithm posted on the secure LRN web site. All LRN laboratories must maintain the competency to pass routine LRN proficiency tests and onsite inspections. In addition to proficiency subscriptions, SCPHL is required to participate in CDC, LRN, and FBI drills and proficiency testing. These drills and tests measure a laboratory's testing personnel, procedures, and laboratory instrumentation. Results are analyzed for accuracy, timeliness, and overall performance, and are available for viewing.

On-site Regulatory Inspections

Every two years, SCPHL is inspected in accord with CLIA. This inspection covers SCPHL's clinical testing, which includes protocols, personnel, equipment, and instruments as well as timely reporting. The inspection report and any corrective actions are documented and are available for viewing.

Every two years, ELAP or a qualified third party performs an on-site inspection of SCPHL to review SCPHL procedures, instrumentation, and personnel for compliance with the National Environmental Laboratories Accreditation Conference Institute standards and California regulations. The inspection report and any corrective actions are documented and are available for viewing.

Proficiency testing: SCPHL subscribes to the College of American Pathologists (CAP), the American Association of Bio-analysts (AAB), the Wisconsin State Laboratory of Health (WSLH), and ERA waters for mandatory and voluntary proficiency testing. All proficiency scores are reported to the appropriate regulatory agency, and are available for viewing.

Annual statistical reports: During the term of this Agreement, the SCPHL shall prepare annual statistical reports of the services provided in relation to specimens originating in Mendocino County.

Procedures manuals: The SCPHL Laboratory Director shall maintain written Procedures Manuals containing Standard Operating Procedures (SOPs) and policies to govern the operations of the SCPHL. The Procedures Manuals shall prescribe the laboratory testing methodologies, sample requirements, test turnaround times, quality improvement/assurance activities, and reporting procedures as required by the relevant regulatory agency. SOPs are available for reference.

Sample requirements, including handling, shipping, and storage, shall be clearly stated in the provided SOPs. Where applicable, turnaround times will be listed on the SCPHL web portal https://socolabportal.sonomacounty.ca.gov/.

SCPHL menu of available tests is listed on the SCPHL web portal https://socolabportal.sonomacounty.ca.gov/.

SCPHL shall provide training for the Orchard web portal for electronic test ordering and report retrieval. SCPHL shall supply a valid user ID and password to access test ordering results online to as many Mendocino staff as requested by Mendocino.

Sonoma shall maintain certification of SCPHL as well as Personnel in a Shipping and Packaging Program. Personnel in the Shipping and Packaging Program are SCPHL staff responsible for sample management, who must maintain certification for laboratory personnel in a shipping and packaging program that meets national and State requirements (e.g., Sample Collection, Packing and Shipping; ShipPack).

SCPHL will package and ship specimens from SCPHL's location to appropriate reference laboratories if testing is not offered in-house.

SCPHL shall provide training for packaging, proper specimen collection, storage, and transport requirements.

Compliance with Public Health Emergency Preparedness. SCPHL will comply with all requirements of the Public Health Emergency Preparedness (hereinafter "PHEP") grant program.

Preventative Maintenance Contracts and Service Agreements. As part of SCPHL's grant requirement, SCPHL shall maintain preventive maintenance contracts and service agreements for equipment and instruments utilized in LRN protocols, procedures, and methods at a minimum. Plans include protocols to ensure that equipment and instruments utilized in LRN protocols, procedures, and methods have been inspected and/or certified according to manufacturer's specifications. These procedures and protocols are inspected by the CDC every three years and/or with unannounced drop-in inspections.

SCPHL Surge Capacity. SCPHL written plans shall include the following considerations for surge capacity:

Options to optimize procedures based on regular and surge personnel, equipment, and facility resources for short-term (i.e., days) and long-term (i.e., weeks to months) response efforts. Options shall also be based on best practices and models available on the LRN web site or other sources.

Triage policies that address how SCPHL shall manage surge testing that may include but not be limited to: Referral of samples to other jurisdictional laboratories.

Prioritization of testing based upon sample type. Prioritization of testing is based upon risk or threat assessment.

Ensuring that SCPHL testing, quality assurance and control review, and reporting can be performed for extended shifts based on need for LRN-B laboratories, if program funds become available.

In the event of an emergency or significant surge in testing needs due to a public health threat, SCPHL may request additional staff and/or other resources from Mendocino County to support lab activities and function in proportion to their testing volume. If Federal or state funds are made available to local health jurisdictions to allow their labs to respond to the

surge in demand for tests, the Parties to this MOU agree to coordinate their request and allocations of resources.

3. Mendocino Roles and Responsibilities

Mendocino shall determine whether a laboratory test should be performed by Sonoma.

Mendocino shall be responsible for packaging all specimens sent to SCPHL. Mendocino shall be responsible for complying with proper specimen collection, storage, and transport requirements. Mendocino shall assume responsibility for handling specimens within approved guidelines for time, temperature, and other critical factors prior to transportation.

Mendocino shall be responsible for ordering tests and retrieving test results via the SCPHL Orchard web portal https://socolabportal.sonomacounty.ca.gov/, and submitting all required submission forms per SCPHL processes.

Mendocino shall be responsible for maintaining HIPAA security of web portal user IDs and passwords issued to Mendocino staff.

SCPHL shall not be responsible for specimens which are improperly packaged or handled prior to courier's pick-up.

Mendocino shall be responsible for transporting or arranging for the transportation of all specimens to SCPHL, located at 3313 Chanate Road, Santa Rosa, CA 95404 (707) 565-4711.

4. Payment

In full consideration of satisfactory performance by Sonoma in providing services required under this MOU, Sonoma shall bill Mendocino for services in accordance with Exhibit B (Budget).

5. Term of MOU

The term of this MOU shall be from July 1, 2024 through June 30, 2029 unless terminated earlier in accordance with the provisions of Section 6 (Termination) below and has no force or effect until fully executed by Mendocino and Sonoma.

6. Termination

- 6.1 <u>Termination</u>. This MOU may be terminated by either party by delivery of a written notice one hundred twenty (120) days prior to the date of termination.
- 6.2 <u>Termination for Cause.</u> Notwithstanding any other provision of this MOU, should either party fail to perform any of its obligations hereunder within the time and in the manner herein provided or otherwise violate any of the terms of this MOU, the other party may immediately terminate this MOU by giving the party failing to perform its obligations written notice of such termination, stating the reason for termination.
- 6.3 <u>Payment Upon Termination</u>. Upon termination of this MOU, Sonoma shall be entitled to receive full payment prorated annually for all services satisfactorily rendered and expenses incurred within the term of the agreement.
- 6.4 <u>Authority to Terminate</u>. The DHS Director has the authority to terminate this MOU on behalf of Sonoma. The County of Mendocino Public Health Director has the authority to terminate this MOU on behalf of Mendocino.

7. Governance

Each County shall have one steering committee representative who is the County Health Officer or other representative as designated by the County. Approval may be by electronic communication.

8. Confidentiality

Both parties agree to maintain the confidentiality of all patient medical records and client information in accordance with all applicable State and Federal laws and regulations.

9. Periodic Reviews

Annual performance evaluations. Evaluation of the performance of the services provided and other obligations required of the Parties under this MOU shall be conducted annually (by September 30th of each year) during this MOU. The annual evaluations shall include, but not be limited to, evaluation of the following: quality of performance, turnaround time and reporting of tests, timely submission of tests and patient information to and from each county, collections results, and satisfaction level of the respective Health Officer or designee of Mendocino with the services provided by the SCPHL.

Annual Fiscal review. Fiscal review of this MOU shall be performed annually. Such reviews shall include review and recommendations for update of the third-party testing fee schedules adopted by the governing boards of each party to this MOU.

Renewal review. All aspects of this MOU shall be reviewed for purposes of negotiating renewal beginning during the 18th month of this MOU, with the results included in the performance evaluation completed during the 24th month of this MOU.

10. Dispute Resolution

If any conflicts or disputes arise between the two parties, involved staff shall meet in a timely manner to resolve the conflict or dispute. It is acknowledged by both parties that the purpose of such meeting is to come to a resolution that is in the best interest of both parties and any client or patient involved.

11. Indemnification

Each party shall indemnify, defend, protect, hold harmless, and release the other, its officers, agents, and employees, from and against any and all claims, loss, proceedings, damages, causes of action, liability, costs, or expense (including attorneys' fees and witness costs) arising from or in connection with, or caused by any act, omission, or negligence of such indemnifying party or its agents, employees, contractors, subcontractors, or invitees. This indemnification obligation shall not be limited in any way by any limitation on the amount or type of damages or compensation payable to or for the indemnifying party under workers' compensation acts, disability benefit acts, or other employee benefit acts. This indemnity provision survives the MOU.

12. Extra or Changed Work

Extra or changed work or other changes to the MOU may be authorized only by written amendment to this MOU, signed by both parties. Minor changes, which do not increase the

amount paid under the MOU, and which do not significantly change the scope of work or significantly lengthen time schedules, may be executed by the Department Head in a form approved by County Counsel. The Board of Supervisors/Purchasing Agent must authorize all other extra or changed work. The parties expressly recognize that, pursuant to Sonoma County Code Sections 1-11, Sonoma personnel are without authorization to order extra or changed work or waive MOU requirements. Failure of Contractor to secure such written authorization for extra or changed work shall constitute a waiver of any and all right to adjustment in the MOU price or MOU time due to such unauthorized work, and thereafter Contractor shall be entitled to no compensation whatsoever for the performance of such work. Contractor further expressly waives any and all right or remedy by way of restitution and quantum meruit for any and all extra work performed without such express and prior written authorization of County.

13. Method and Place of Giving Notice, Submitting Bills and Making Payments

All notices, bills, and payments shall be made in writing and shall be given by email, personal delivery, or by U.S. Mail or courier service. Notices, bills, and payments shall be addressed as follows:

TO SONOMA COUNTY: Public Health Laboratory

Attn: Dr. Rachel Rees, Director

County of Sonoma Department of Health Services

3313 Chanate Road Santa Rosa, CA 95404 Phone 707-565-4711 Facsimile (707) 565-7849

Rachel.rees@sonoma-county.org

TO MENDOCINO COUNTY: Jenine Miller, Psy. D.

Public Health Director

County of Mendocino Public Health, 1120 South Dora St Ukiah, CA 95482

Phone 707.472.2341

millerie@mendocinocounty.gov

When a notice, bill or payment is given by a generally recognized overnight courier service, the notice, bill or payment shall be deemed received on the next business day. When a copy of a notice, bill or payment is sent by facsimile, the notice bill or payment shall be deemed received upon transmission as long as (1) the original copy of the notice, bill or payment is promptly deposited in the U.S. mail, (2) the sender has a written confirmation of the facsimile transmission, and (3) the facsimile is transmitted before 5 p.m. (recipient's time). In all other instances, notices, bills and payments shall be effective upon receipt by the recipient. Changes may be made in the names and addresses of the person to whom notices are to be given by giving notice pursuant to this paragraph.

14. Merger

This writing is intended both as the final expression of the MOU between the parties hereto with respect to the included terms and as a complete and exclusive statement of the terms of the MOU. No modification of this MOU shall be effective unless and until such modification is

evidenced by a writing signed by both parties. The parties agree and understand that in the event a request is received from a county to be added as a party to this MOU, a factor in said consideration shall be review of the costs set forth in Exhibit B (Budget).

§ The remainder of this page has intentionally been left blank. §

IN WITNESS WHEREOF

| | CONTRACTOR/COMPANY NAME |
|---|---|
| DEPARTMENT FISCAL REVIEW: | D. |
| By: | By: Tina Rivera, County of Sonoma |
| Jenine Miller, Public Health Director | Tina Rivera, County of Conoma |
| D . | Date: |
| Date: | NAME AND ADDRESS OF CONTRACTOR: |
| Budgeted: X Yes No | TV WE THE RESILEGE OF GOTTIMOTOR. |
| Budget Unit: 4013 | Sonoma County Department of Health Services |
| Line Item: 86-2189 | Public Health Laboratory Attn: Dr. Rachel Rees, Director |
| Org/Object Code: PNCDIZ | 3313 Chanate Road |
| Grant: Yes No | Santa Rosa, CA 95404 |
| Glant. Tes No | |
| COUNTY OF MENDOCINO | By signing above, signatory warrants and |
| | represents that he/she executed this Agreement |
| By: | in his/her authorized capacity and that by his/her |
| Maureen Mulheren, Chair BOARD OF SUPERVISORS | signature on this Agreement, he/she or the entity upon behalf of which he/she acted, executed |
| BOARD OF SOFERVISORS | this Agreement |
| Date: | Ğ |
| ATTEST: | COUNTY COUNSEL REVIEW: |
| DARCIE ANTLE, Clerk of said Board | APPROVED AS TO FORM: |
| By: | |
| Deputy | D ₁ , |
| I hereby certify that according to the provisions of | By: COUNTY COUNSEL |
| Government Code section 25103, delivery of this | |
| document has been made. | Date: |
| DARCIE ANTLE, Clerk of said Board | |
| By: | |
| Deputy | |
| INSURANCE REVIEW: | EXECUTIVE OFFICE/FISCAL REVIEW: |
| By: | Ву: |
| By: Risk Management | By: Deputy CEO or Designee |
| Date: | Date: |
| Signatory Authority: \$0-25,000 Department; \$25,001-50,000 Pu | rchasing Agent; \$50,001+ Board of Supervisors |
| Exception to Bid Process Required/Completed EB# Mendocino County Business License: Valid Exempt Pursuant to MCC Section: Government Entity | |

Exhibit A. Scope of Work

INCLUDED SERVICES

SCPHL shall provide diagnostic, analytical, and investigative laboratory support included in this scope of work to Mendocino County epidemiologists, healthcare providers, law enforcement, and environmental health, to help determine cause and origin of as well as definitively characterize a public health incident.

SCPHL provides the following Title 17 and diagnostic clinical specimen testing and technical assistance services:

Bacteriology

Molecular Diagnostics

Mycobacteriology

Mycology

Serology

Sexually Transmitted Infections

Tick-borne Diseases

Virology

SCPHL provides the following environmental specimen testing and technical assistance services:

Rabies

Water (Recreational and drinking waters)

Tick Testing for Lyme Disease

New Testing Services - Mendocino's requests for new tests not currently on the SCPHL list of available tests may be developed in consultation with the SCPHL Director and Health Officers or Deputy Health Officers from each county. The SCPHL Director will assess feasibility and develop a cost analysis and time frame for implementation.

Special Handling - SCPHL will perform "STAT" testing at the request of either the Sonoma or Mendocino Health Officer or designee.

SCPHL Business Office and Hours - SCPHL is open Monday through Friday 8 a.m. to 5 p.m. SCPHL observes the following holidays, but maintains minimal staffing or on-call staffing to conduct routine and unexpected testing requests.

New Year's Day

Martin Luther King, Jr. Day

Lincoln's Birthday

Presidents' Birthday

Cesar Chavez Day

Memorial Day

Independence Day

Labor Day

Veteran's Day

Thanksgiving Day and day after

Christmas

Processing Time and Testing Results - SCPHL will process the specimen and report results within the times indicated on the SCPHL SOPs for each test. SCPHL will provide web-based reporting of test results and supply a valid user ID and password to access test results online.

Testing for Public Health Threats or Emergencies - In cases where a county's Health Officer or designee has determined that a test or tests are required in order to respond to a public health emergency or threat, SCPHL will make every effort to process the specimen within the requested turn around time. In cases where there are multiple, competing priorities, the SCPHL Director will consult with the Health Officer or designee of the affected counties. In the case of a federally declared emergency, the two parties agree to share the allocated relief funds in proportion to the respective workloads, share and maintain efforts sufficient to meet the demand of lab testing and diagnosis.

Coordinate non-LRN-B Testing and Analysis for Routine and Surge Capacity- SCPHL agrees to comply with all requirements of the PHEP to coordinate with the applicable lead agency for testing of chemical, radiological, nuclear, and explosive samples utilizing CDC-established protocols and procedures (e.g., LRN), where available and applicable, to provide detection, characterization, and confirmatory testing to identify public health incidents. This testing may include clinical and environmental samples.

EXCLUDED SERVICES

Requests for molecular sequencing (e.g., SARS-CoV-2 sequencing for variant determination), wastewater surveillance, and other non-diagnostic molecular epidemiologic lab testing support performed at SCPHL shall be considered extra work and billed separately according to the SCPHL fee schedule for that year. The laboratory requisition or other written or email communications will serve as authorization for testing and billing.

SCPHL does not bill patient private insurance, Medi-Care, or Medi-Cal.

§ The remainder of this page has intentionally been left blank. §

Exhibit B. Budget

Sonoma has initially set the cost of its services to Mendocino at \$100,000 in the first year. If the executed date of the MOU does not cover a full fiscal year, the first invoice shall reflect a prorated cost based on the executed date of the MOU.

Cost shall increase in each of the next four years by 3.8%.

| FY* | Total from Previous FY (\$) | Cost Adjustment % from Previous FY | Annual Cost Adjustment (\$) | Total (\$) |
|---------|--------------------------------|--|--------------------------------|---------------|
| 2024-25 | NIA | NIA | NIA | 100,000 |
| 2025-26 | 100,000 | 3.8 | 3,800 | 103,800 |
| 2026-27 | 103,800 | 3.8 | 3,944 | 107,744 |
| 2027-28 | 107,744 | 3.8 | 4,094 | 111,838 |
| 2028-29 | 111,838 | 3.8 | 4,249 | 116,088 |
| Total | | | | 539,470 |

Sonoma shall send invoices on an annual basis. Invoices are payable by Mendocino upon receipt.

Sonoma shall directly bill test requests from hospitals or any private party to the third-party submitter at the County of Sonoma Board of Supervisors-approved fee.

Payments under this MOU shall not exceed five hundred thirty-nine thousand four hundred twenty dollars for the term of this MOU.