

Public Health Laboratory Agreement
Sonoma and Mendocino Counties

County of Sonoma Contract No. 2020-1119-A00

MEMORANDUM OF UNDERSTANDING

Between

County of Sonoma

and

County of Mendocino

This Memorandum of Understanding (hereinafter "MOU"), dated as of OCTOBER 6TH, 2020 (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. SCPHL services are presented in the attached Exhibit A, Scope of Work, made a part of this MOU by reference.

With respect to any identifiable information concerning a client under this contract that is obtained by Sonoma, Sonoma agrees to comply with applicable regulations for HIPAA and shall hold Mendocino harmless from any sanctions received by Sonoma, to the extent permitted by law, for breach of these regulations. Sonoma (1) will not use any such information for any purpose other than carrying out the express terms of this contract, (2) will promptly transmit to Mendocino all requests for disclosure of such information not emanating from the client, and (3) will not disclose, except as otherwise specifically permitted by this contract or authorized by the client any such information to any party other than Mendocino without prior written authorization specifying that the information is releasable.

3. Mendocino Roles and Responsibilities

Mendocino will determine whether a laboratory test should be performed by Sonoma. Mendocino is responsible for packaging of all specimens sent to SCPHL. Mendocino shall designate a specimen pick up location, and submit all required submission forms and is

responsible for complying with proper specimen collection, storage and transport requirements. Mendocino will assume responsibility for handling specimens within approved guidelines for time, temperature and other critical factors prior to transportation. Mendocino will provide the names and contact information necessary to receive web-based reporting of test results.

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, 2020 through December 31, 2020 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 Termination. 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 Payment Upon Termination. 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.

6.3 Authority to Terminate. The County of Sonoma Department of Health Services Director has the authority to terminate this MOU on behalf of Sonoma. The County of Mendocino Health & Human Services Director has the authority to terminate this MOU on behalf of Mendocino.

7. 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.

8. Performance Standards

Sonoma shall follow procedures approved by CLIA, ELAP, and the LRN in providing these public health laboratory services. 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 quality control procedures deemed necessary by the State Department of Health during the term of this MOU.

9. 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.

10. 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.

11. 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.

12. 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 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
Facsimile (707) 565-7849

TO MENDOCINO COUNTY:

Mary Alice Willeford, HHSA Assistant Director
County of Mendocino Health and Human Services Agency
Public Health Services
1120 South Dora St
Ukiah, CA 95482

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.

13. 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, the parties hereto have executed this MOU as of the Effective Date.

DEPARTMENT FISCAL REVIEW:

By: Tammy Moss Chandler
Tammy Moss Chandler, HHS Director

Date: 9/17/2020

Budgeted: ☒ Yes ☐ No

Budget Unit: 4013

Line Item: 86-3113

Org/Object Code: PNADMIN

Grant: ☐ Yes ☒ No

COUNTY OF MENDOCINO

By: John Haschak
JOHN HASCHAK, Chair
BOARD OF SUPERVISORS

Date: OCT 07 2020

ATTEST:

CARMEL J. ANGELO, Clerk of said Board

By: Sandey Daugherty
Deputy OCT 07 2020

I hereby certify that according to the provisions of Government Code section 25103, delivery of this document has been made.

CARMEL J. ANGELO, Clerk of said Board

By: Sandey Daugherty
Deputy OCT 07 2020

INSURANCE REVIEW:

By: Carmel J. Angelo
Risk Management
Date: 09/10/2020

CONTRACTOR/COMPANY NAME

By: Russell W. Carpenter
Russ Carpenter
Sonoma County

Date: 12/14/2020

NAME AND ADDRESS OF CONTRACTOR:

Public Health Laboratory
Attn: Dr. Rachel Rees, Director
County of Sonoma
Department of Health Services
3313 Chanate Road
Santa Rosa, CA 95404

By signing above, signatory warrants and represents that he/she executed this Agreement in his/her authorized capacity and that by his/her signature on this Agreement, he/she or the entity upon behalf of which he/she acted, executed this Agreement

COUNTY COUNSEL REVIEW:

APPROVED AS TO FORM:

CHRISTIAN M. CURTIS,
County Counsel

By: Christian M. Curtis
Deputy
Date: 09/10/2020

EXECUTIVE OFFICE/FISCAL REVIEW:

By: Darcie Arille
Deputy CEO
Date: 09/10/2020

Signatory Authority: \$0-25,000 Department; \$25,001- 50,000 Purchasing Agent; \$50,001+ Board of Supervisors

Exception to Bid Process Required/Completed ☐

Mendocino County Business License: Valid ☐

Exempt Pursuant to MCC Section: _____

Exhibit A. Scope of Work

Sonoma Department of Health Services operates its SCPHL under the supervision of the SCPHL Director, who is qualified under CLIA to act as a public health laboratory director, and Sonoma is willing to provide laboratory services to regional county partners.

SCPHL will:

- Maintain adequate equipment and facilities and sufficient personnel to carry on dependable public health laboratory work.
- Employ procedures and reporting practices consistent with all applicable laws.
- Establish and maintain for a minimum of two years adequate record systems and files of laboratory work done.
- Conduct, maintain, and operate programs for controlling the quality of test performance.
- Demonstrate satisfactory performance in a proficiency testing program.

Specimen Testing Services

SCPHL provides the following specimen testing and technical assistance services to its regional partners:

Bacteriology
Molecular Diagnostics
Mycology
Serology
Shellfish & Water
Mycobacteriology
Tick-borne Diseases
Virology
Rabies

SCPHL menu of available tests is listed on the SCPHL web site (<http://www.sonoma-county.org/health/services/laboratory.asp>).

Sample requirements, including handling, shipping, and storage, will be clearly stated on the SCPHL web site (<http://www.sonoma-county.org/health/services/laboratory.asp>). Where applicable, turnaround times will be listed on the SCPHL web site (<http://www.sonoma-county.org/health/services/laboratory.asp>).

Water Testing – SCPHL outlines specifics related to water testing, storage, and transportation on the SCPHL web site (<http://www.sonoma-county.org/health/services/laboratory.asp>).

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.

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 turnaround time. In cases where there are multiple, competing priorities, the SCPHL Director will consult with the Health Officer or designee of the affected counties.

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

Transportation – SCPHL is responsible for transporting or arranging for the transportation of specimens to SCPHL, located at 3313 Chanate Road, Santa Rosa, CA 95404. The specific requirements for each test can be found on the SCPHL web site (<http://www.sonoma-county.org/health/services/laboratory.asp>). SCPHL is not responsible for specimens which are improperly packaged or handled prior to courier's pick up.

Laboratory 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 specimens which arrive at SCPHL by 10 a.m. the same day of arrival. SCPHL will process the specimen and report results within the times indicated on the SCPHL web site (<http://www.sonoma-county.org/health/services/laboratory.asp>) 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.

Microbiologist Training – Within available resources, SCPHL will pursue opportunities to use SCPHL for training microbiologists.

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

Perform Sample Management – SCPHL will implement Laboratory Response Network (hereinafter "LRN") established protocols and procedures where available and applicable [and other mandatory protocols, such as those for the International Air Transport Association (hereinafter "IATA") and the U.S. Department of Transportation (hereinafter "DOT")] for sample collection, handling, packaging, processing, transport, receipt, storage, retrieval, and disposal.

Maintain Certification of Laboratory Personnel in a Shipping and Packaging Program – SCPHL staff responsible for sample management 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).

Conduct 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, food, and environmental samples.

Laboratory Surge Capacity – SCPHL written plans should include the following considerations for surge capacity:

- Options to optimize procedures based on regular and surge personnel, equipment, and facility resources for short-term (e.g., days) and long-term (e.g., weeks to months) response efforts. Options should also be based on best practices and models available on the LRN web site or other sources.
- Triage policies that address how SCPHL will manage surge testing that may include:
 - Referral of samples to other jurisdictional laboratories
 - Prioritization of testing based upon sample type
 - Prioritization of testing based upon risk or threat assessment
 - Contingencies to assure newborn screening in a surge situation. Newborn screening can be assured by memoranda of agreement or contracts with commercial vendors ensuring that SCPHL testing and reporting can be performed for extended shifts based on need for Level 1 and Level 2 LRN-C laboratories.
- Ensuring that SCPHL testing, quality assurance and control review, and reporting can be performed for extended shifts based on need for LRN-R laboratories, if program funds become available.

Preventative Maintenance Contracts and Service Agreements – As part of SCPHL's grant requirement, SCPHL is to 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.

Competency for LRN-B Testing Methods – As an active member of the LRN, SCPHL is designated as a level-B reference laboratory. SCPHL maintains competency for LRN-B testing methods by having the ability to test for select agent/sample types/tests listed in the high-risk, environmental-sample testing algorithm posted on the secure LRN web site.

LRN Proficiency Tests – 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.

Support Public Health Investigations – SCPHL shall provide analytical and investigative support to epidemiologists, healthcare providers, law enforcement, environmental health, food safety, and poison control efforts to help determine cause and origin of as well as definitively characterize a public health incident.

In addition to the LRN requirements detailed above, SCPHL is inspected every year by the State of California - Environmental Laboratory Accreditation Program (hereinafter "ELAP"). The ELAP review happens annually and covers all aspects of our drinking and recreational water

testing. The inspection report and any corrective actions are documented and are on-site for viewing.

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

Every year, the State of California requires split-sample testing for all of SCPHL dairy personnel. These results are compared to other dairy labs in the State and reviewed for intra-laboratory agreement.

Every two years, CLIA performs an on-site inspection of SCPHL to review SCPHL procedures, instrumentation, and personnel for compliance with standard methods.

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.

Billing Clients and Third-Party Payors – This agreement is strictly between the County of Sonoma and the County of Mendocino. Sonoma shall bill Mendocino for services in accordance with Exhibit B (Budget). And Sonoma will not bill Mendocino any additional amounts for laboratory testing requests made by Mendocino that are not set forth in Exhibit A (Scope of Work). Test requests from hospitals or any private party will be billed at the County of Sonoma Board of Supervisors-approved fee.

Exhibit B. Budget

Mendocino County – Cost is calculated at the Fiscal Year 2019-2020 rate plus 3.5%.

Period	Annual Cost + Annual Cost Adjustment	Total
July 1, 2020 – December 31, 2020	$\frac{\$126,228 + (\$126,228 \times 3.5\%)}{2}$	\$65,323
Total		\$65,323

Invoices will be sent on a quarterly basis and are payable upon receipt.