

EXHIBIT A

CLINICAL LABORATORY SERVICES

1. GENERAL: Contractor shall provide clinical laboratory test services as requested by Director for mental health patients/clients treated at directly-operated clinics/programs. Contractor shall maintain at all times qualified personnel, equipment, and supplies to perform the services under this Agreement, including, but not limited to, the following:

A. At regularly scheduled times as well as on an as needed or STAT basis, Contractor shall provide phlebotomy services for mental health patients/clients at the clinics/programs (e.g., drawing of blood samples for specific test(s), etc.). STAT basis is defined as services which are requested at once by the mental health clinics/programs.

B. Contractor shall transport all test specimens under adequately controlled conditions to Contractor's clinical laboratory(ies) for testing and analysis and submit documented results by computerized reports to County's physician who ordered the particular test at the clinic/program.

C. Contractor shall analyze routine tests according to Exhibit B (TEST PRICE LIST) and shall analyze STAT tests as soon as possible.

D. Contractor shall report routine test results as specified in Exhibit B to the concerned clinic/program according to the reporting requirements set forth in Paragraph 9 (REPORTING REQUIREMENTS) of this Exhibit. In the case of STAT tests, results shall be reported by documented telephone report or other equally rapid and available means (e.g., computer printout, facsimile copy, etc.) to the concerned clinic/program as

soon as the test is completed, and a written report to County's physician who ordered the particular test at the clinic/program shall follow.

E. Contractor's laboratory director and personnel shall be available to County staff for consultation regarding receipt, performance, results, and both methodological and clinical interpretation of results of laboratory testing.

F. Contractor and its staff shall conform to all applicable County rules and regulations while conducting clinical laboratory tests for patients/clients of County on County premises.

2. DEFINITIONS: As used in this Agreement, the following terms shall have the following meanings:

A. Turn-Around Time: For routine laboratory tests, it shall be the interval between the time the specimens are picked up (a routine schedule pick up time established by Director for each clinic) and the time the printed result(s) is (are) returned to the concerned clinic; and for STAT laboratory tests, the interval from the time Contractor is notified that a STAT specimen is available for pick up to the time that the printed result is transmitted and produced on a printer in the concerned clinic/program or a documented telephone result is reported to the concerned clinic/program when a printer is not available in the concerned clinic/program.

B. Holiday: State and nationally recognized holidays, including, but not necessarily limited to, New Year's Day, Dr. Martin Luther King, Jr.'s Birthday, President's Birthday (combined Lincoln's and Washington's Birthdays), Memorial

Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving weekend, and Christmas Day.

C. STAT Service: Upon receipt of a request to provide clinical laboratory services at once, Contractor shall: (1) immediately dispatch a special representative to pick up the specimen, (2) perform the test as rapidly as possible, (3) report the result by computer terminal printout to the concerned clinic/program or by documented telephone report or other equally rapid and available means (e.g., computer printout, facsimile copy, etc.) as soon as the test is completed; and (4) return a written copy of the reported tests to such clinic/program according to the same reporting requirements set forth in this Agreement.

D. Full-Time Personnel: Normally present in the laboratory between the hours of 8:00 a.m. and 5:00 p.m., Monday through Friday, except on holidays.

E. Test Price List: List of tests and fees shown in Exhibit B (TEST PRICE LIST).

3. PERSONNEL REQUIREMENTS: In addition to other laboratory personnel requirements defined by Federal or State law, or both, the following personnel requirements are applicable:

A. Contractor shall have one or more full-time laboratory directors who shall be a physician, M.D., licensed to practice medicine in the applicable State from which services are to be rendered, and shall further be Board certified in Anatomical and Clinical Pathology. More than one full-time laboratory director may be used to fulfill both requirements.

Director shall be given written notice within 30 days of any change in the laboratory director(s) or staff pathologist. Such notice shall include the new laboratory director's or new staff pathologist's current curriculum vitae.

B. Contractor shall at any time have sufficient numbers of full-time applicable State licensed physician, M.D.s and Ph.D.s commensurate with the complexity, diversity, and quantity of tests performed at that time.

C. Contractor's laboratory director and personnel shall be available to County staff for consultation regarding receipt, performance, results, and both methodological and clinical interpretation of results of laboratory testing.

4. INSPECTIONS: Contractor shall make its personnel, facilities, and techniques available for inspection at reasonable times without prior notice by authorized representatives of Director, County's Auditor-Controller, Joint Commission on Accreditation of Hospital Organizations (JCAHO), the State Department of Mental Health, and/or the State of California Department of Health Services, if applicable.

5. QUALITY CONTROL AND QUALITY ASSURANCE: Contractor shall have an ongoing system of quality control and keep quality control records for each laboratory test it performs which shall include, but are not necessarily limited to: (1) methods for determination of accuracy consistent with national quality and performance standards and (2) participation in national proficiency testing programs. County representatives, duly authorized by Director, shall have access to these records when such access is required for the administration or audit of this Agreement. In addition, Contractor shall

be prepared to provide details of its procedures, including documentation of source material, accuracy, sensitivity, specificity, and precision for each test provided; and Contractor shall provide accurate information regarding proper conditions for collecting test samples, including proper preservation and of samples, as well as information on patient conditions, medications, or other alterations of the sample which may interfere with tests results or other proper interpretation of tests results.

Contractor shall also have an ongoing quality assurance program that allows Director to review and monitor Contractor's performance.

Contractor's quality assurance program shall be approved in writing by Director, and shall include, but not necessarily be limited to: (1) providing Director access to original clinical material (e.g., County patient/client slides), of which there shall be no numeric or categorical limitations, within 48 hours if of a clinical significance and within five (5) days if for quality assurance purposes upon notification by Director to Contractor and (2) acceptance from Director and assaying of either blind, blind duplicates, or unknown clinical specimens, the results of which may provide the basis for continuation or discontinuation of this Agreement.

6. TEST AVAILABILITY: All tests shall be completed and the results made available as quickly as possible. Except for those tests which may be performed by the Subcontractors approved by County under Paragraph 27 (SUBCONTRACTING) of the body of this Agreement, all tests specified in Exhibit B shall be performed by Contractor's laboratory.

7. EQUIPMENT AND SUPPLIES: Contractor shall provide all equipment and supplies necessary to perform all services under this Agreement.

Contractor shall provide all vials, bottles, and other supplies required to stabilize samples and maintain sample integrity in transit to its laboratory. Such supplies shall be provided as needed by the clinic and at no additional cost to County. All supplies regularly available to Contractor's regular commercial customers shall be available to County.

8. TELEPHONE CONSULTATION SERVICE: Contractor shall maintain a consultation service in order to respond to direct telephone queries from clinic/program staff regarding a specific specimen or test result. This service shall be available 24 hours per day, seven (7) days per week.

9. REPORTING REQUIREMENTS:

A. Computerized or written reports of test results shall be in a format which can be entered directly into the individual patient/client charts in the concerned clinic/program. Each report shall contain all data and information as specified by JCAHO, the State of California Department of Health Services, and Federal guidelines. The reports shall require no additional processing or additional data entry prior to posting on patient/client chart.

B. Telephone reports shall be made in addition to required computerized or written reports:

(1) On tests requiring 24 hours turn-around-time, when the 24-hour period terminates at a time when the concerned clinic is closed.

(2) On any individual test if requested by Director as specified in Exhibit B (TEST PRICE LIST).

C. Written reports of tests with a specified turn-around-time of greater than 24 hours shall be delivered to the concerned clinic/program within the specified turn-around-time.

D. Payment for a test requested hereunder shall be disallowed for each incomplete report, or for failure to observe a specified reporting protocol, or for any test that is not reported in the manner or time specified in this Agreement, unless: (1) turn around time requested by the concerned clinic/program is shorter than specified herein, (2) specimen processing is delayed due to illegible, ambiguous, improper or otherwise unclear test requisition, or where (3) acts of God or nature, beyond the control of Contractor or County, are the cause.

E. Report of Quality Control Data: If requested by a Director, Contractor shall provide a report of quality control procedures for tests performed by individual cytotechnologists.

10. STAT REQUIREMENTS: STAT level service shall be provided by Contractor. STAT service, if requested by Director, shall be provided 24 hours per day, seven (7) days per week. If STAT reports are requested at once by telephone, the telephone number of the concerned clinic/program shall be used, immediately followed by a written report to such clinic/program, which shall include all required information.

11. ROUTINE PICK UP SERVICE REQUIREMENTS: A regularly scheduled pick-up service shall be provided by Contractor for each clinic/program. This shall include pick-up

each day between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, holidays excepted. The frequency of pick-up shall be one time per day at a predetermined time that is approved by Director.

12. BILLING AND AUDIT REQUIREMENTS:

- (1) Patient's/client's name (last, first, middle initial).
- (2) Patient's/client's identification number (i.e., DMH IS number), date of birth, Social Security Number, primary insurance information (i.e., third-party payor source).
- (3) Patient's/client's location (clinic/program address), ordering physician.
- (4) Date and test(s) requested, performed reported.
- (5) Date and time specimen was received in laboratory performing test. Laboratory's written report may be attached to specimen log to comply with this requirement.
- (6) Date results reported to clinic. Laboratory's written report may be attached to Specimen Log to comply with this requirement.
- (7) Cost of each test performed and reported.
- (8) Date and time test received and reported by Contractor.
- (9) Laboratory performing work if other than Contractor's laboratory.
- (10) Contract turn-around time.
- (11) Credits, if any.

B. Clinical Laboratory Requisition Form: Each clinic/program shall prepare a Clinical Laboratory Requisition Form for each patient/client receiving services

hereunder, completing accurate patient/client identifying information that will allow the Contractor to verify patient's/client's Medi-Cal eligibility prior to billing the Department as the payor of last resort; shall retain a copy of the Clinical Laboratory Requisition Form in the patient's/client's chart; and shall forward a copy of the Clinical Laboratory Requisition Form to the Accounting Division. Contractor shall also retain a copy of each Clinical Laboratory Request Form, which shall contain at the minimum:

- (1) Date test requested and date specimen obtained.
- (2) Name of clinic/program.
- (3) Name and address of the laboratory performing the service.
- (4) Patient's/client's name and identification number (i.e., DMH IS number), date of birth, Social Security Number.
- (5) Signature of attending County physician, M.D.
- (6) Test(s) or panel name.
- (7) Method of payment: County, Medi-Cal, Medicare, private insurance, HMO, other.

C. Monthly Billing Statement:

(1) Contractor's monthly billing statement shall be separated by each clinic/program site and shall include at least the following in addition to the other requirements of this Agreement:

- a. Date of service.
- b. Patient/client name and identification number (i.e., DHM IS

number).

- c. Name of test and the charge for each test.
- d. Verification of Medi-Cal Eligibility Response.
- e. Summary page:
 - i. Month of service.
 - ii. Total amount payable identified by each clinic/program site.
- f. Credits, if any.

(2) Contractor shall submit the monthly billing statement to the Accounting Division no later than the 15th day of the month following the month the test was provided.

D. Third-Party Payors: Contractor shall be responsible for verifying Medi-Cal and Medicare eligibility and directly billing Fee-For-Service Medi-Cal and Medicare for services. Verification of Medi-Cal Eligibility Response must accompany the request for payment. Contractor shall maintain verifiable records as to each such patient's/client's name, date and type of laboratory services rendered, and shall be willing to accept Medi-Cal/Medicare reimbursement as full payment for Medi-Cal/Medicare eligible clients.

Contractor shall bill and collect fees for clinical laboratory services rendered to Medi-Cal and Medicare eligible patients/clients and to patients/clients with other health care insurance coverage. Verification of denial must accompany the request for

payment by the Department of Mental Health before the Department reimburses Contractor for denied third-party payor claims.

E. Test Price List: Contractor shall provide clinical laboratory services and submit statements only according to the TEST PRICE LIST (Exhibit B) approved by Director and as otherwise requested by Director. All tests shall be considered quantitative and qualitative assays by the County physician, M.D. ordering the test(s) unless otherwise expressly noted.

The Director shall conduct a review of clinical laboratory tests performed which are not included on the TEST PRICE LIST (Exhibit B) and which County physicians determine as necessary.

ExhibitA-ClinicalLabAgreement
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