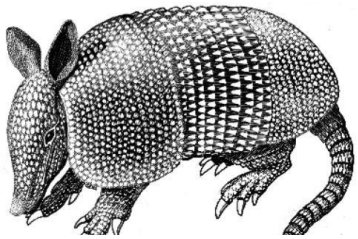
POINT OF CARE TESTING DEPARTMENT

University of California San Francisco

Reference Guide

Point of Care Testing
in
Clinical Research



UCSF POINT OF CARE TESTING

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Part 1. POCT General Information

- **Definition**: Point-of-care testing (POCT) is defined as laboratory testing that takes place at or near the site where the patient is located. Commonly known as bedside testing, near-patient testing, alternate site testing, and ancillary testing. The College of American Pathologists (CAP) describes POCT as 'testing that does not require permanent dedicated space and it refers to those analytical patient testing activities provided within the institution but performed outside the physical facilities of the main clinical laboratories. POC testing falls under the federal CLIA regulations.

- Clinical Laboratory Improvement Amendments (CLIA) is a federal regulation that establishes quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results. CLIA applies to all laboratories that examine "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease" or "the assessment of the health of, human beings." (42. U.S.C. § 263a(a)). These examinations also include "procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body" (42 C.F.R. § 493.2). ***Depending on the circumstances, research testing can be either exempted from CLIA or subject to CLIA. Most testing performed in the confines of clinical 'research' falls under the domain and hence requirements of CLIA. Testing facilities may qualify to be exempted from CLIA certification if they meet the description of "research laboratories" provided by the CLIA regulations at 42 C.F.R. § 493.3(b)(2).***

- **POCT Tests as Medical Devices**: According to section 201(h) of the Federal Food Drug and Cosmetic Act, a medical device is an instrument intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals. All POCT instrumentation and kits are medical devices and are subject to regulatory controls by the FDA (U.S. Food and Drug Administration). The FDA categorizes commercially marketed tests into one of three CLIA categories according to complexity and their potential for risk to public health: waived and non-waived (moderate complexity and high complexity tests).

  CLIA waived devices are the least complex. In order to receive CLIA Waived status, a manufacturer must demonstrate that a device is simple to use, has low risk to public health, and that an untrained person can get accurate results by reading the instructions. To determine a device's waived status, visit the CLIA Waived Analyte database on the FDA website at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.

  Non-waived testing is a term used to refer collectively to moderate and high-complexity testing. Laboratories or sites that perform these tests need to have a CLIA certificate, be inspected, and must meet the CLIA quality standards described in 42 CFR Subparts H, J, K, and M.

- **Waived Testing**: Non-critical tests which have been approved by the FDA for home use employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or pose no reasonable risk of harm to the patient if performed incorrectly. Waived test lists are constantly updated and can be viewed on the web at

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Categorization_of_Tests.html

☐ **Non-Waived Testing:**

- Moderately Complex Testing: Tests which require minimal scientific and technical knowledge and training to perform accurately, operational steps are either automatically executed or easily controlled, and minimal interpretation and judgment are required.
- Highly Complex Testing: Tests which require specialized scientific and technical knowledge, training and experience to perform accurately, operational steps require close monitoring or control, and extensive independent interpretation and judgment are required.

☐ **CLIA and Research:** Depending on the circumstances, research testing can be either excepted from CLIA or subject to CLIA. Most testing performed in the confines of 'research' at UCSF and affiliates falls under the domain and hence requirements of CLIA. Testing facilities may qualify to be exempted from CLIA certification if they meet the description of "research laboratories" provided by the CLIA regulations at 42 C.F.R. § 493.3(b)(2).

A) Included Under domain/regulations of CLIA (examples):
   1) Testing performed to determine eligibility for drug administration or invasive procedure (i.e. HCG, urine drug screen, hemoglobin, hematocrit, creatinine)
   2) Testing performed to determine which study arm study subject is enrolled in.
   3) Testing performed and resulted to study subject or individual involved in study subject's clinical care which has known clinical significance.

B) Not included under CLIA:
   1) Testing performed on study subject-derived sample which is to be used solely for data analysis and will not affect the study-subject's study interventions in any way

AND

   2) Result of test NOT shared with patient and/or individual involved in study subject's clinical care.

OR

   3) Any facility or component of a facility that only performs testing for forensic purposes.

OR

   4) Laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed which meets SAMHSA guidelines and regulations. However, all other testing conducted by a SAMHSA-certified laboratory is subject to this rule.

☐ **POCT in an Organization**: Generally, large volume testing in main, centralized laboratories is efficient due to its low cost per test. However, in some clinical situations, low testing cost at the expense of extended turnaround time is unsuitable for care needs. In these cases, POC fulfills the

requirement for expedited turnaround times, such as in situations where more rapid initiation of proper care management can produce improved medical outcomes and results. While POC testing usually involves a higher unit of cost when compared to testing in the main laboratory, improved operational efficiency can be considered a potential positive outcome and can also lead to lower costs - especially if this results in decreased length of stay in critical areas such as emergency departments, intensive care units, and operating rooms.

Although POC is generally regarded as relatively simplified testing, regulatory compliance is identical to main lab testing. It therefore is governed by regulatory agencies, including (in California) the California Department of Public Health (CDPH) and for non-waived testing labs, accrediting bodies such as the Joint Commission or the College of American Pathology (CAP). A Point of Care program or department, under the guidance of the medical director, is responsible for maintaining standard compliance in all spheres of POC testing at the pre-analytical, analytical, and post-analytical level.

The goals of a POCT program include:

- To ensure point of care testing is high quality and cost effective
- To ensure all POCT follows regulatory and organizational standards
- To provide guidance to all testing personnel and potential users for POCT
- To provide a standardized policy for all POCT performed in the organization

A Point of Care program works to uphold these goals by functioning to:

- To ensure point of care testing is high quality and cost effective
- Assist with platform/kit selection
- Provide routine laboratory surveillance and inspection
- Oversee quality assurance measures for all analytical levels of POCT
- Ensure prompt corrective action for any compliance deficiencies
- Perform training and competency to POC testing personnel
- Perform method validations
- Ensure CLIA/CDPH compliant on ordering and resulting practices

Part 2. POCT Clinical Research Guidelines

A. LICENSING

All sites performing laboratory testing are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88). These sites must be licensed in order to perform any testing; no testing should ensue prior to obtaining a CLIA license. CLIA has granted deemed status to approved accreditation organizations and allow these entities to accredit or license testing sites.

Many of POCT procedures are identified under CLIA as waived. A site performing only waived tests must have a "Certificate of Waiver" license. All waived testing must strictly adhere to the manufacturer's instructions for test performance as well as any individual health care facility or system's rules and policies.

To obtain a CLIA/CDPH license, visit this link for more information: https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/ClinicalandPublicHealthLaboratories.aspx

B. REGULATORY REQUIREMENTS

All sites performing POCT in a Clinical Research must be authorized to do so by the UCSF POCT West Bay Regulatory Oversight Team for each test performed. All testing is performed only by authorized users who have been trained and deemed competent to perform specified procedures and meet state and federal regulations required to perform testing. Below are the requirements:

1. Lab Director Requirements: Federal and State law dictates level of education and/or licensing requirements for lab directors*. A lab director may delegate some responsibilities to technical or clinical consultant (non-waived testing).

2. General Supervisor Requirements: A laboratory director of a clinical laboratory performing waived tests may delegate or reapportion his or her responsibilities, as allowed by Section 1209 of the Business and Professions Code, by utilizing a waived laboratory supervisor. A waived laboratory supervisor shall:

    (1) Be listed in Section 1206.5 of the Business and Professions Code; and
    (2) Possess at least a baccalaureate degree from an accredited college or university; and
    (3) Have at least one year of training or experience in clinical laboratory testing in those tests or examinations that he or she will be supervising; and
    (4) Document competency in those tests he or she will be supervising to the laboratory director at least semiannually during the first year and annually, or whenever new instrumentation is added, thereafter.

3. Test Operator Requirements: Federal and State law dictates level of education and/or licensing requirements for test operators*

4. Validation/Verification Studies: Federal and State law dictates components and frequency of validation/verification studies required*

5. Operational requirements:

    a. Standard operating procedure with CLIA required elements signed by lab director.
    b. Training/competency documentation of test operators with content meetings CLIA requirements at interval appropriate for testing being performed*
    c. Quality control performed at frequency required by manufacturer and/or CLIA*
    d. Instrument maintenance performed as required by manufacturer.
    e. Temperature monitoring of reagents, kits, and/or devices as required by manufacturer.
    f. Proficiency Testing if required*.
    g. Order/Resulting: CLIA complaint order and result documentation must be completed and retained for at least three years.

    *Tests are designated a level of complexity by FDA (waived vs non-waived (moderate complexity vs high complexity) and requirements are stricter for increasing complexity of testing.

C. ADDITIONAL GUIDELINES

1. Any UCSF Research entity that performs POCT and within the UCSF West Bay and its affiliates must conform to state and federal regulations.

2. If the analyte for research is already being tested at UCSF using an equivalent assay, it is required that the CLIA compliant POCT assay/platform already in place will be used. The UCSF assay will be considered the CLIA compliant assay. The sponsor-required (considered to be non-compliant) assay/platform can be run in parallel; it is recommended that the non-compliant assay/platform closely follow all manufacturer recommendations including quality control frequency and temperature monitoring. If the CLIA-compliant assay and the non-CLIA compliant assay results agree, no further action is required. If the results don't agree, then a sample should be obtained and sent to the main lab for further investigation; additionally, the POC medical director of the UCSF West Bay should be informed of the discrepancy.

3. Any proposals to request for a new test/analyte using a Point of Care assay will need to be reviewed and approved by the UCSF POCT Committee. If determined to be necessary for the study and approved for use by the UCSF POC Committee, the POC oversight team at UCSF West Bay will work with the study team to determine the next steps. The UCSF West Bay POC team will work with the study team to ensure CLIA-complaint implementation. The service offered by the POC West Bay POC team may be recharged to the study budget; for more information regarding recharge rates in Section VII. For questions regarding which recharge rates might apply, contact UCSF West Bay Operational Lead.

4. The timeline to implement a Point of Care Test all depends on the test requested and whether a CLIA license already exists. A waived test already in use at UCSF can likely be implemented in 4-6 weeks if the site already has an appropriate CLIA license. If a waived testing CLIA license (called a Certificate of Waiver) needs to be obtained, it could take up to 3-6+ months as obtaining the license from CA CDPH can be a slow process. If the testing is waived but not already in use at UCSF, the POC team will need to generate the required materials, implementation may take up to 2-3 months. If the testing is not already in use at UCSF and is non-waived, if approved by the POC Committee, anticipate at least 6-8+ months for all required studies to be performed.

5. The performing research entity is required to fulfill all the POCT Test Requirements and Testing Procedures as outlined in PART 3.C.

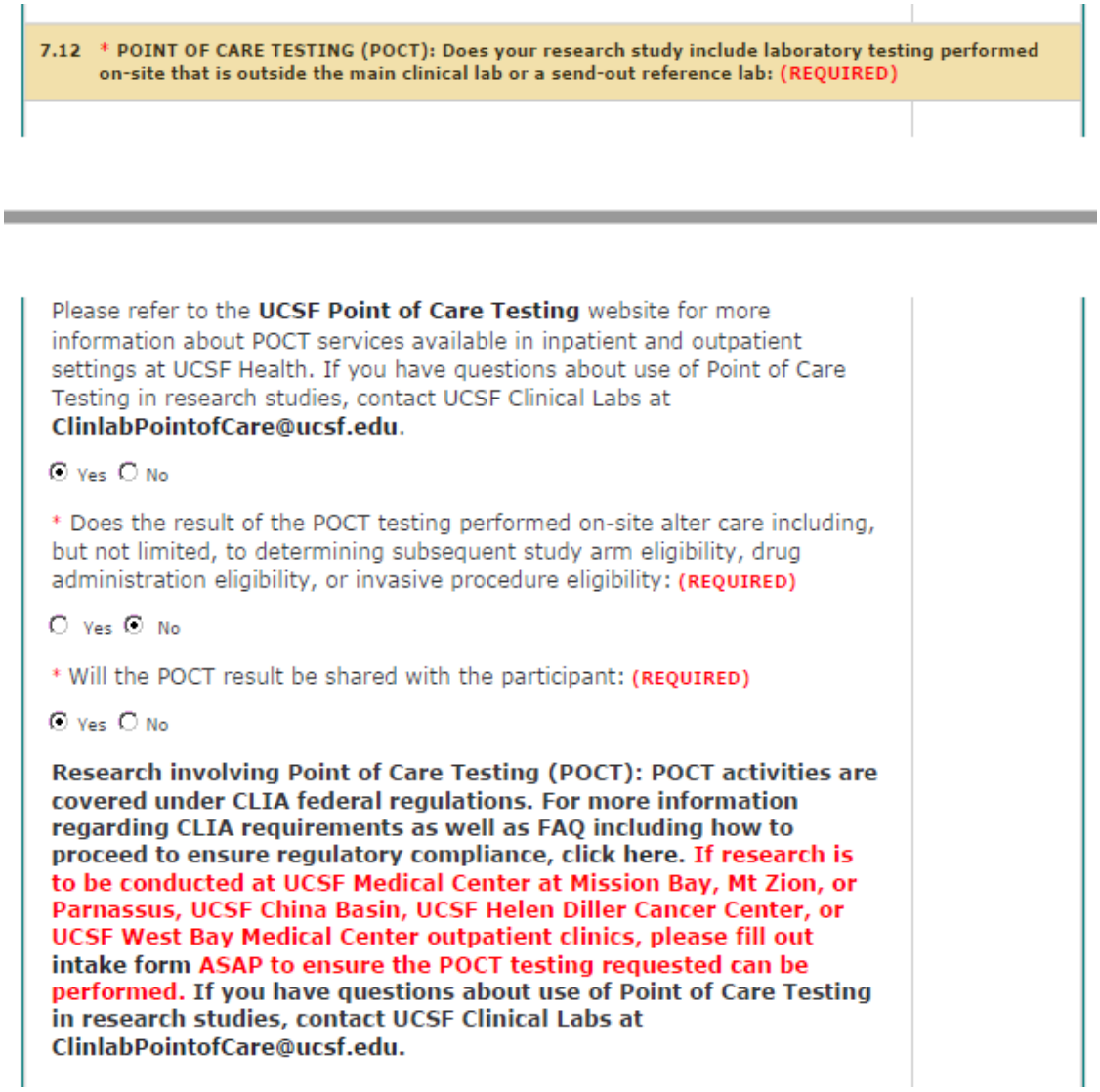
Part 3. UCSF Clinical Research New Study Steps

A. IRB PROCEDURE – POCT QUESTIONNAIRE

1. UCSF Research entities are required to respond in their Study Application if study:
    i. Includes Point of Care Testing (POCT)
    ii. Result of POCT will alter care or eligibility of either the study, administration, or procedure.
    iii. Results will be shared with the participant.

    If answers to either questions ii or iii, are "Yes", the Research entity should proceed with the second step.

    If answers are "No", there are no further steps involved for the Research entity and Point of Care Testing department on their Study Application.



B. POCT RESEARCH INTAKE FORM

Research entity must fill out the POCT Research Intake Form. This form is submitted to our UCSF POCT West Bay Regulatory Oversight Team to determine steps to compliance as resources allow.

C. POCT REQUIREMENTS

After receiving a response from the UCSF POCT West Bay Regulatory Oversight Team, the following items must be established if they haven't already been established within the Clinical Research Center or Research location where the study is being conducted. The UCSF POCT West Bay Team will initiate to get these completed.

a. Training and Competency of Performing POCT Operators

1) A designated individual, meeting CA requirements, for waived testing supervisor affiliated with the research study, is responsible for the supervision of POCT Waived Testing as allowed by CLIA and CA law and regulations. Examples of individuals who may fulfill this role include the research coordinator (if with the required education and experience), a study affiliated RN nurse manager, or the study's primary investigator. More information regarding CA regulations on this topic can be found here:

   Section 1036.3 - Waived Laboratory Supervisor, Cal. Code Regs. tit. 17 § 1036.3 | Casetext Search + Citator

2) Training – Initial (Waived and Nonwaived)

   a) Personnel performing testing must undergo training and be evaluated for correct and appropriate performance.

   b) Training is performed before testing personnel performs or reports any patient testing results on new methods and instruments.

   c) Records and evidence for training on each platform must be maintained for personnel for three years beyond when testing is discontinued.

3) Waived and Nonwaived Competency Assessment

   a) First assessment takes place after training is complete and individual has begun testing on their own.

   b) Waived testing requirement – initial, six-months, and annual assessment

      b.1.) **Five** waived competency elements must be used as determined by the POCT program and laboratory director.

         i. Direct observation of routine patient testing, including patient preparation (if applicable), specimen handling, specimen processing, and testing.
         ii. Monitoring the recording and reporting of test results
         iii. Review of quality control records and preventive maintenance records
         iv. Direct observation of instrument maintenance and function checks
         v. Assessment of problem-solving skills.

   c) Nonwaived Competency Assessment - initial, six-months, and annual assessment

      c. 1.) **Six** nonwaived competency elements must be used as determined by the POCT program and laboratory director.

i. Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen collection, handling, processing, and testing.
ii. Monitoring, recording, and reporting of test results.
iii. Review of intermediate test results or worksheets, quality control, proficiency testing, and preventive maintenance performance.
iv. Direct observation of performance of instrument maintenance function checks and calibration.
v. Assessment of test performance as defined by laboratory policy.
vi. Assessment of problem-solving skills as appropriate to the job.

d) Documentation of competency must be completed for each individual operator and must include sign off with assessor's name and date.

e) Competency assessment documents are retained for at least 3 years.

b. Test Requirements

1. Supplies

Supplies are ordered by the Research entity through their study sponsor or UCSF Bear Buy.

2. Quality Control

i. Manufacturer requirements must be followed, ensuring controls performed as required by procedure.

ii. Staff must review controls for acceptability prior to reporting patient results.

iii. Ensure internal controls are documented for each patient test, or as required by manufacturer.

iv. Ensure monthly QC review is performed and documentation reviewed by supervisor (log sheets).

3. Maintenance

i. Manufacturer maintenance requirements must be followed as required by device.

ii. Ensure monthly maintenance review is performed and documentation reviewed by supervisor (log sheets), if applicable.

4. Temperature Monitoring

Each unit/clinic performing POC testing must monitor/record the temperature of areas where POCT supplies are stored at least on a daily basis. Monitoring must consist of:

i. Applicable temperatures per supply storage requirement (refrigerated and/or room temperature).

ii. Retrospective temperatures reflect continuous temperature monitoring of devices (Min/Max temperature thermometers or automated temperature monitoring devices). This can be performed manually or via automated temperature monitoring system, as applicable to the POCT site.

iii. Unit must verify and ensure temperatures fall within the acceptable ranges for the reagents, kits, and or device.

iv. Temperature monitoring logs/records must be reviewed monthly by supervisor. Corrective actions must be performed and documented if values are outside of the acceptable limits.

NOTE: For more information about our POCT Temperature Monitoring SOP and logs, please visit our Temperature Monitoring page in our intrasite.

c. Research Patient Testing Procedures

1.) **Ordering**

Research entity must ensure that each POC test is accompanied by a test requisition signed by an authorized provider. For UCSF affiliates, please refer to each SOP in our POCT Intrasite for test order information in APEX. For Research entity that will not order tests in APEX, please utilize Appendix A as the Requisition form for the POCT order.

2.) **Patient Testing**

Sample collection and patient testing must be followed according to the POCT Standard Operating Procedure (SOP). Please refer to each SOP found in our POCT Intrasite for more information on the specific test procedures.

3.) **Resulting**

Each POC test must be resulted either through the POC device's interface connectivity to the electronic health record system or manual enter/edit reporting in the electronic health record system by the performing POC staff.

POCT Research Result forms may be used if results are not entered into EMR as part of regular clinical workflow. Please see Appendix B and C for the POCT Research Result forms. It is highly recommended that these forms be scanned into the EMR. If unscanned, the POCT Research Result forms must be kept for a minimum of 3 years or longer.

d. Self-Audits

Federal and state regulations require that sites performing Point-of-Care testing adhere to manufacturer's requirements and regulatory agencies. To assure ongoing compliance with these requirements, Self-audits should be performed by the Research entity where the current research study is conducted.

Site audits include, but are not limited to, reviewing any items/standards related to quality control (performance, review, and documentation), supply management (proper dating, documentation, and storage), administrative, patient testing and regulatory compliance.

Please refer to Appendix D for the Monthly Self-Audit Form.

For Clinical Research Center that is already audited by our POCT Coordinator, they will be exempted from requirement to perform the Self-Audit.

D. RECHARGE FEES

The services offered by the UCSF POCT West Bay team may be recharged to the study budget. Below are our current recharge fees. Fees are subject to change without prior notice.

POCT Research Recharge Fees

POCT Service	Pricing
Approved Waived Test (Test Kits - no connectivity)	$309.00
Approved Interfaced Device - Waived	$2,565.00

*Approved Interfaced Device - Non-Waived	$3,088.00
New Platform - Waived Testing (research only/no validation)	$1,094.00
New platform - Waived Testing (with validation)	$3,611.00
*New Platform - Non-waived Testing	$5,180.00
Training and competency (waived test) - per 30 min. session	$66.00
Training and competency (non-waived test) - per 60 min. session	$131.00

*If project is extended, additional fees may apply.

E. RESOURCES

UCSF (UCSF West Bay and UCSF B-Oak) East Bay and its affiliate campuses (SFGH, SF VA) have designated Point of Care testing departments who are tasked with CLIA/CA regulatory oversight of Medical Center activities. If your testing will occur within a Medical Center location (aka. a building in which patients are seen for classic clinical care), it may be appropriate for your team to work with the site-specific POC team to ensure regulatory compliance; see below for contact information to discuss your case further. Alternatively, depending which site the POC studies are being conducted, you may need to independently work to achieve regulatory compliance, including procuring your own CLIA license and following all CLIA requirements before study subject testing can proceed.

UCSF West Bay

POC Operational Lead (preferred first contact): Mary Basmayor (Mary.Basmayor@ucsf.edu)

POC Medical Director: Dr. Anne Deucher (Anne.Deucher@ucsf.edu)

UCSF East Bay (Benioff Oakland)

POC Operational Lead: Kellie Graham (Kellie.Graham@ucsf.edu)

POC Director: Dr. Jon Rowland (Jon.Rowland@ucsf.edu)

SFGH

POC Operational Lead: Shannon Kastner (Shannon.Kastner@ucsf.edu)

POC Medical Director: Dr. Barbara Haller (Barbara.Haller@ucsf.edu)

SF VA

POC Operational Lead: Gina Torres (Gina.Torres@va.gov)

POC Medical Director: Dr. Mark Lu (Mark.Lu@va.gov)

Additional resources:

Training and Competency - ACRT@ucsf.edu (Ambulatory Care Resource Team)

Questions related to POCT Research - ClinlabPointofCare@ucsf.edu

Information on CLIA and Research and links on our POCT forms - Research | POCT Research (ucsf.edu)

UCSF Regulatory Affairs offers access to the TJC's Hospital and Laboratory Accreditation Standards E-edition online at: https://psra.ucsfmedicalcenter.org/joint-commission

POC SOPs – Standard Operating Procedures (SOP) | UCSF Point of Care Testing (VPN needed or should be logged within the UCSF server)

POC Forms and logs – Forms & Logs | UCSF Point of Care Testing (VPN needed or should be logged within the UCSF server)

POCT Training and Competency Checklists – Training and Competency Checklist | UCSF Point of Care Testing (VPN needed or should be logged within the UCSF server)

POCT FAQs – Troubleshooting and FAQs | UCSF Point of Care Testing (VPN needed or should be logged within the UCSF server)

https://www.jointcommission.org/

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia

F. REFERENCES

https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/research-testing-and-clia.pdf

https://www.cdc.gov/clia/test-complexities.html

https://www.cms.gov/regulations-and-guidance/legislation/clia

https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/FacilityLicensingHome.aspx

https://www.cdc.gov/labquality/waived-tests.html

https://barrins-assoc.com/tjc-cms-blog/hospitals/refresher-waived-testing-requirements/

APPENDIX

Appendix A – Requisition Form

UCSF Health
Clinical Laboratories
Point of Care Testing

Patient Name: (Last, First)

Patient Label (If applicable):

DOB: (MM/DD/YYYY)

Sex:

MRN:

UCSF Clinical Laboratory Requisition - Point of Care Testing Performed in Clinical Research

Ordering Provider*: *(First and Last Name)*

Ordering Department:

UCSF Provder ID (if applicable):

**The requesting provider must be licensed to practice in California.*

Specimen Information

Collection Date:

Collection Time:

Collected By:

Specimen Source:

Additional Collection Instructions:

Test Request

Hematology / Coagulation Tests

☐ Hemoglobin (Hemocue)	WB
☐ Hemoglobin (Avoximeter)	WB
☐ Oxyhemoglobin Saturation (Avoixmenter)	WB
☐ ACT-LR (Hemochron Elite)	WB
☐ ACT-Plus (Hemochron Elite)	WB
☐ INR (Coaguchek XS)	WB

Chemistry Tests

☐ Glucose (NOVA Statstrip)	WB
☐ Creatinine (iSTAT)	WB
☐ Hemoglobin A1C (DCA Vantage)	WB
☐ Occult Blood (Cologuard Manual Kit)	Stool
☐ Gastric Occult Blood (Gastroccult Manual Kit)	*
☐ pH (Body Fluid)	Container/ Specimen

* Gastric aspirate

Additional Tests

☐ Please use below space and fill out full name of the test(s) requested. ->

Urine Tests

☐ Urinalysis (Clinitek)	Urine Cup
☐ hCG, Urine (Manual Kit - Cardinal Health)	Urine Cup
☐ Urine Drug Screen (Manual Kit)	Urine Cup

Blood Gas / Electrolytes Panel

☐ ABLOR Panel (ABL 90 Flex Plus) (Blood Gas, Electrolytes, Hct/Hgb, Glu, Lac)	WB
☐ EG7+ Panel (iSTAT) (Blood Gas, Electrolytes, Hct/Hgb)	WB
☐ CG8+ Panel (iSTAT) (Blood Gas, Electrolytes, Hct/Hgb, Glucose)	WB
☐ CHEM8 Panel (Piccolo) (Electrolytes, TCO2, Glu, BUN, Crea)	WB

Respiratory / Infectious Disease

☐ COVID-19 (Molecular - ID NOW)	Nasal/NP
☐ Influenza A and B (Molecular - ID NOW)	Nasal/NP
☐ COVID-19, Rapid Ag (Manual Kit)	Nasal/NP
☐ Strep A (Manual Kit - Acceava Rapid)	Throat
☐ RSV (Manual Kit- Binax)	NP
☐ HIV 1/2 Ag & Ab Combo (Manual Kit - Alere)	WB

For questions related to lab requisition, please reach POCT team via the contacts below.
Mission Bay -> Email: ClinlabPOCTMB@ucsf.edu or tel# 415.514.2144
Parnassus and MZ -> Email: ClinlabPOCTParn@ucsf.edu or tel# 415.514.8223

Please visit UCSF Clinical Lab - POCT Website for additional infomation: **https://poct.ucsf.edu**

Appendix B – Manual Test Form

UCSF Health, Clinical Laboratories, San Francisco, CA

UCSF Health **CLINICAL STUDY POCT LAB RESULT FORM**

Scan into APEX under Scan Clinical Docs; do not result using manual APEX POC module		
Patient MRN/ ID:	Location:	Ordering Physician:
		Test(s) Ordered:
Patient Name:	DOB:	CLIA Director and Lab Address:
Unit #:	Date/Time Collected:	

CIRCLE and/or FILL in APPROPRIATE ORDER AND RESULTS. For critical results, document call/notification under comments.

TEST: Cardinal Health Pregnancy Test *Normal Range: Negative*	RESULT:	Comments:
TEST: Acceava Rapid Strep A Test *Normal Range: Negative*	RESULT:	Comments:
TEST: Binax RSV *Normal Range: Negative*	RESULT:	Comments:
TEST: Coloscreen *Normal Range: Negative*	RESULT:	Comments:
TEST: Gastroccult *Normal Range: Negative*	RESULT:	Comments:
TEST: Quickvue COVID-19 Rapid Antigen *Normal Range: Negative*	RESULT:	Comments:
TEST: ALERE HIV1/2 AG & AB COMBO *Normal Range: Non-Reactive* *Normal Range: Non-Reactive*	RESULT: HIV 1/2 Ag: HIV 1/2 Ab:	Comments:
TEST: Coaguchek XS INR *Normal Range: 0.9 - 1.2*	RESULT:	Comments:
TEST: DCA Vantage HA1C (Hemoglobin A1C) *Normal Range: 4.2 - 6.0 %*	RESULT:	Comments:
TEST: pH, Body Fluid *Normal Range: Not defined as per SOP*	RESULT:	Comments:

Urinalysis	Multistix 10 SG		Comments:
Test:	***Normal Range:***	**RESULT:**	
Glucose (Urine)	*Negative*		
Bilirubin (Urine)	*Negative*		
Ketone (Urine)	*Negative*		
Specific Gravity (Urine)	*1.001 - 1.035*		
Blood (Urine)	*Negative*		
pH (Urine)	*4.6 - 8.0*		
Protein (Urine)	*Negative*		
Urobilinogen (Urine)	*0.2 - 1.0*		
Nitrite (Urine)	*Negative*		
Leukocyte Esterase(Urine)	*Negative*		

Urine Drug Screen	CLIAwaived IDTC Drug Screen		Comments:
Test:	***Normal Range:***	**RESULT:**	
Amphetamine	*Not Detected*		
Barbiturates	*Not Detected*		
Benzodiazepines	*Not Detected*		
Cocaine	*Not Detected*		
MDMA	*Not Detected*		
Methamphetamine	*Not Detected*		
Methadone	*Not Detected*		
Opiates	*Not Detected*		
Oxycodone	*Not Detected*		
PCP	*Not Detected*		
Buprenorphine	*Not Detected*		

POCT OPERATOR NAME: _____ EID: _____

Appendix C – Interfaced Devices Form

UCSF Health, Clinical Laboratories, San Francisco, CA

UCSF Health **CLINICAL STUDY POCT LAB RESULT FORM**

Scan into APEX under Scan Clinical Docs; do not result using manual APEX POC module		
Patient MRN/ ID:	Location:	Ordering Physician:
Patient Name:	DOB:	Test(s) Ordered:
		CLIA Director and Lab Address:
Unit #:	Date/Time Collected:	

CIRCLE and/or FILL in APPROPRIATE ORDER AND RESULTS. For critical results, document call/notification under comments.

TEST: Glucose (NOVA Statstrip) *Normal Range: (Adult) 70-199 mg/dL (Neonate) 55 - 115 mg/dL*	RESULT:	Comments
TEST: Hemoglobin (Hemocue) *Normal Range →* ***Male > 18 years: 13.6-17.5 Female > 15 years: 12.0-15.5***	RESULT:	Comments: Reference range listed refer to normal adults. Refer below for hemoglobin references range for different ages and gender.
TEST: COVID-19 (ID NOW) *Normal Range: Not Detected*	RESULT:	Comments
TEST: Creatinine (iSTAT) *Normal Range: 0.4-1.5 mg/dL*	RESULT:	Comments
TEST: ACT-LR (Hemochron Elite) *Normal Range: 131 - 178 seconds*	RESULT:	Comments: Reference range listed refer to normal adults. For pediatric applications, see Hemochron Elite SOP.
TEST: ACT-PLUS (Hemochron Elite) *Normal Range: 81 - 125 seconds*	RESULT:	Comments: Reference range listed refer to normal adults. For pediatric applications, see Hemochron Elite SOP.

Urinalysis	**Clinitek - POC Urine Panel**		Comments
Test:	*Normal Range:*	RESULT:	
Glucose (Urine)	*Negative*		
Bilirubin (Urine)	*Negative*		
Ketone (Urine)	*Negative*		
Specific Gravity (Urine)	*1.001 - 1.035*		
Blood (Urine)	*Negative*		
pH (Urine)	*4.6 - 8.0*		
Protein (Urine)	*Negative*		
Urobilinogen (Urine)	*0.2 - 1.0*		
Nitrite (Urine)	*Negative*		
Leukocyte Esterase (Urine)	*Negative*		

Oximetry	**AVOX 4000 - Whole Blood Oximetry**		Comments: * Refer below for hemoglobin references range for all age group and gender.
Total Hemoglobin	*Reference Range**	*RESULT:*	
Oxyhemoglobin Saturation	*Normal Range: 93 to 100%*	*RESULT:*	

Electrolytes / Blood Gas		**Check the following→ □ ABL90 □CHEM8 □EG7 □CG8+**			**Specimen Source:**
Test:	**Result:**	**Reference Ranges**	**Test:**	**Result:**	**Reference Ranges**
pH		**Arterial:** 7.35 to 7.45 **Venous:** 7.29 - 7.41	Sodium, WB (mmol/L)		*136 - 146*
pCO2 (mmHg)		**Arterial:** (<1 year old) 27 - 41 ; >1 year old: 32 - 46 **Venous:** 37 - 55	Chloride, WB (mmol/L)		*99 - 106*
pO2 (mmHg)		**Arterial:** (<30 days old) 80 - 100 ; (>30 days old) 83- 108 **Venous:** N/A	Potassium, WB (mmol/L)		*Arterial: 3.4 - 4.5 Venous: 3.7 - 4.7*
HCO3 (Bicarbonate) (mmol/L)		**Arterial:** 23.0 - 29.0 **Venous:** 23.0 - 31.0	Ionized Calcium, WB (mmol/L)		*Arterial: 1.13 - 1.27 Venous: 1.12 - 1.32*
Base Excess/Deficit (mmol/L)		**Arterial:** -3.0 to +3.0 **Venous:** N/A	Total CO2, iSTAT (mmol/L)		*0-15 yrs old: 16 - 30 >15 yrs: 22 - 32*
O2 Saturation		**Arterial:** 95 - 100 **Venous:** N/A	Anion Gap, iSTAT (mmol/L)		*4 - 14*
Total Hemoglobin (g/dL)		*Refer below for hemoglobin references range for different ages and gender.*	BUN, iSTAT (mg/dL)		*0 - 4 yrs: 6 - 27 >4 yrs: 6 - 22*
Hematocrit			Creatinine, iSTAT (mg/dL)		0.6 - 1.3
Glucose, WB Whole Blood (mg/dL)		*Normal Range: (Adult) 70-199 mg/dL (Neonate) 55 - 115 mg/dL*	Lactate, WB (mmol/L)		*0.4 - 24.0*

Comments: Listed reference range for above blood gas and electrolytes values are from ABL 90 SOP. Reference ranges for ages/gender/ different cartridges not listed, refer to specific iSTAT SOPs.

*Hemoglobin Reference Range g/dL: 0 – 7 days: 14.5 – 22.5, 8-14 days: 13.5 – 21.5, 2 – 4 weeks: 12.5 – 20.5, 1 – 2 months: 10.0 – 18.0, 2 – 3 months: 9.0 – 14.0, 3 – 6 months: 9.5 – 13.5, 6-24 months: 11.0-13.5, 2-5 years: 11.2-13.5, 5-8 years: 11.4-15.5, 8-12 years: 11.6-15.5, Male 12-15 years: 12.3-16.0, Male 15-18 years: 12.6-17.0, **Male > 18 years: 13.6-17.5, Female 12-15 years: 11.8-15.5, Female > 15 years: 12.0-15.5**

POCT OPERATOR NAME: _____ **EID:** _____

Appendix D – Monthly Self-Audit Form

Monthly Self Audit Form
UCSF Health, Clinical Laboratories, San Francisco, CA

UCSF Health | MONTHLY SELF-AUDIT | FORM-0545, REV. 08 | Page 1 of 7

Waived Testing Monthly Audit

Please email audit results to ClinLabPOCTParn@ucsf.edu. Audits must be completed and returned by the 7th of each month.

Test	Test Kit/ Vial				Notes/ Policy
	Lot #/ Serial #	Expiration Date	Opened/ QC'ed Date	Date/Initials (Y/N)	
Multistix 10SG (test strip)					*QC on the initial opening of test strips. Test strips are good until the exp date on the bottle. Repeat QC of strips monthly when in use for more than a month.*
Level 1 Control					
Level 2 Control					
(Uristix) if applicable					
ColoScreen (slide/ card)					*QC must be performed after opening each new box of slides, and annually thereafter if is still in use.*
Coloscreen Developer					
Urine Pregnancy (Box)					*QC must be performed when a new box of test kits is opened and monthly thereafter if the box is still in use.* *The control set is good until the expiration date on the box.*
Control Set					
Glucometer (Serial #)					*QC when a new vial of the strip is opened. QC on each day of use. QC vials are good for 3 months upon opening, and test strips are good for 6 months upon opening.*
Glucose Test Strip					
Level 1 Control					
Level 3 Control					
CoaguChek XS (Serial #)					*Change code key with each new box of strips. Test strips are good until the manufacturing exp date.*
Test strips					
PPMP					*Check saline and KOH daily when in use. Discontinue use if cloudy.*
Saline Solution					
KOH Solution					
DCA Vantage					*Optics check every 3 months. Run reagent Cal. card and both levels of QC upon opening of the new box. QC weekly and new lot. Cartridges are good to exp date if refrigerated or 90 days at RT.*
Cartridge					
Controls					
HemoCue					*QC daily when in use. Cuvettes are good for 3 months at RT, and controls are good for 30 days once opened. When receiving a new lot of control, contact POCT immediately to update QC ranges.*
Microcuvettes					
Control 1					
Control 3					
Clinitek Status Plus					*QC on the initial opening of test strips. Test strips are good until exp. date on bottle. Repeat QC of strips monthly when in use more than a month.*
Level 1 Control					
Level 2 Control					
ID Now Covid-19 Ag					*QC when the kit is opened - QC is good until the expiration date on the box.*
Positive Control					
Negative Control					
ID Now Influenza A/B					*QC when the kit is opened - QC is good until the expiration date on the box.*
Positive Control					
Negative Control					
Acceava Strep A					*Run internal QC for each patient testing. Test dipsticks are good for 12 months from open date. External QC new kit, and for every new reagent or new canister of dipsticks.*
Test Dipsticks					
Extraction Reagent 1					
Extraction Reagent 2					

UCSF Health

MONTHLY SELF-AUDIT

Test	Test Kit/ Vial				Notes/ Policy
	Lot #/ Serial #	Expiration Date	Opened/ QC'ed Date	Date/Initials (Y/N)	
Alere HIV 1/2 Ag & Ab Combo					*QC when kit is opened; Every 3 months; when storage/ testing area temperature fails.*
Combo Kit					*Combo Test cards and Buffer must be stored at **2-30°C** until expiration date. If stored refrigerated, ensure that Test Units are brought to operating temperature, 15-30°C (59-86°F), before performing testing.*
Combo Controls					*QC is stored at 2- 8°C and is good until the expiration date on the box.*
BinaxNow RSV					*RSV Test kits with QC stored in **room temp** (15- 30 C) are stable until the manufacturer's expiration date on the box.* *QC when a new box is opened, after 1 year if the kit is still in use.*
Test kit					
Positive					
Negative					
CLIA Waived Urine Drug Test					*Dipcards are stored at room temperature in the original sealed pouch; stable until the expiration date printed on the pouch. Controls stored 2-8ºC, stable until the box's expiration date. Once opened, store refrigerated and stable for 31 days.*
Dip Cards					
Negative Control					
Positive Control					
Oraquick Advance Rapid HIV Ab					*Test kits are stored at room temp or (2-8 C; unopened kits are stable until the manufacturer's expiration date on the box. QC stored 2-8 C. Unopened QC stable until the expiration date printed on the box. Opened QC vials are stable for **8 WEEKS**.*
Test kit					
Control Set					
Quickvue SARS Ag Test					*QC when the kit is opened – QC and Kit are good until the expiration date on the box.*
Test Kit (with built-in QC)					
Negative Control Swab					
Positive Control Swab					
pH Strips					*store in their original container at room temperature. Avoid excessive heat and moisture, stable until the expiration date printed on its original packaging or for 2 years after QC date, whichever comes first.*

Standard	Yes or No	Comment
Quality Control performed and passed according to SOP policy.		
Documentation for QC and Temp Logs were completed and documented correctly.		
QC Logs require review by the manager or designee.		
Testing Personnel have competencies assessed at the required frequencies.		
Patient Testing performed and resulted according to the applicable SOP policy.		
Infection Control measures are practiced and inspected for patient safety.		

Performed By: _____ Reviewed By: _____ Score:

Copied: _____ Location: _____

POCT Self Audit Checklist (Waived & Non-Waived Testing)		
Unit/Clinic Location:	Audited by:	
CLIA Number and Approved Test(s):	Date:	
POCT STANDARD - Quality Control	**YES / NO / N/A**	**Comments/Notes**
• All quality controls for POCT supplies/devices are performed promptly (per SOP specifications and requirements) and 'pass' before patient testing.		
• QC log has corrective action documented for EACH 'out of range' QC result		
• All QC results are documented in the QC log for each test.		
• The monthly review of QC logs are completed by the practice manager or designee (initialed/signed and dated).		
POCT STANDARD - Supply Management	**YES / NO / N/A**	**Comments/Notes**
• All POCT supplies are clearly labeled with date opened (month/day/year) and user initials.		
• If applicable, POCT supplies are clearly labeled with a new expiration date upon opening or storage temperature change. ○ *For example, opening a Nova StatStrip control changes the expiration date from what is listed to 3 months.*		
• All POCT supplies are used within expiration date. No expired supplies in testing area.		
• All POCT supplies are stored correctly according to the manufacturer's recommendation and SOP.		
• QC lot numbers and testing material lot numbers match those documented in the QC log.		
POCT STANDARD - Administrative	**YES / NO / N/A**	**Comments/Notes**
• Testing log entries are documented correctly for each entry. ○ *Example - Serial numbers of ESV wands, LQC lot numbers, etc. are correctly entered into the instrument.*		
• Proper nomenclature, guidelines, and correction of clerical errors are followed. ○ *Example - Proper QC log entries [use POS/NEG and not +/-], use black or blue ink only, no whiteout on documents, etc.*		
• "Not In Use/NIU" or "Closed" is documented on days when patient testing is not performed and QC not required. ○ *Note: This applies to all logs - waived testing, maintenance, manual temperature logs, etc. - with the days of the month prefilled.*		

POCT STANDARD - Personnel	YES / NO / N/A	Comments/Notes
• The competency of personnel performing testing is assessed at the required frequency. POCT documentation available. *Note: Waived testing is performed at initial training and annually thereafter; non-waived testing is performed at initial, 6-month, and annually thereafter.*		
POCT STANDARD – Patient Testing	**YES / NO / N/A**	**Comments/Notes**
• If applicable, critical results are repeated and/or sent to the lab for confirmation per SOP specifications, if applicable. *Example - All initial critical glucose (Nova StatStrip) results must be repeated. If the repeat is still in critical range, a sample must be sent to the main lab for confirmation testing. See Nova StatStrip SOP (POCT Intranet Page) for additional details.*		
• Critical results are properly documented. *Example - In addition to repeating and main lab confirmation, all critical glucose (Nova StatStrip) results must have a comment entered ('Will repeat test,' 'Notified MD/NP,' 'Lab Draw')*		
• Patients and patient tests are properly identified using the correct patient identifiers/medical record numbers.		
POCT STANDARD - Infection Control Surveillance	**YES / NO / N/A**	**Comments/Notes**
• The unit inspects and maintains laboratory equipment and testing area, such as required preventive maintenance,- to reduce risk of infection and patient safety related occurrences.		
• Infection control procedures are properly followed according to the SOP. *Example - ALL steps of the cleaning/disinfecting procedure for Nova StatStrip (excerpt from POCT SOP-5450) are performed by all users:* *1. Wipe the external surface of the meter thoroughly with a fresh germicidal disinfecting bleach wipe.* *2. Using a fresh new germicidal bleach wipe, wipe the surface of the meter (top, bottom, left, and right sides) a minimum of 3 times horizontally followed by 3 times vertically avoiding the barcode scanner and electrical connector. Gently wipe the surface area of the test strip port making sure that no fluid enters the port.* *3. Ensure the meter surface stays wet for 1 minute and is allowed to air dry for an additional 1 minute. Glucometers use on patients with enteric precautions need a 3 minute wet time to ensure microbial kill.* *4. Dispose of used wipe and gloves in a standard biohazard container.* *5. Wash your hands thoroughly with soap and water, and put on a fresh set of protective gloves before proceeding to perform testing on the next patient.*		

POCT STANDARD – Temperature Monitoring	YES / NO / N/A	Comments/Notes
• If manual monitoring, temperature logs values are within the acceptable range for refrigerator/freezers/room temperature.		
• If manual monitoring, temperature logs have corrective action for out of range entries.		
• If on automated temperature monitoring system, manual temperature monitoring was performed during alerted downtime.		
• Digital Min/Max thermometers (in use and those being stored as back-up) are within calibration.		
Notes/Comments:		

Self-Audit Reviewed By: _____ Date: _____