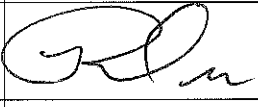

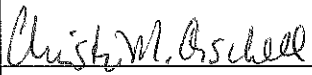


Clinical and Translational Support Laboratory

Maintenance of Work Areas

SOP No./WI No.: CTSI-CRC-PL-103
 Department: Processing Laboratory
 Version No.: 02
 Effective Date: 05 Jan 2017
 Supersedes: No.: CTSI-CRC-PL-103-01 Effective Date: 01 May 2014
 Page No: 1 of 4
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Signature			
Date	23 Dec 2016	28 Dec 2016	Dec 29, 2016



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1. OBJECTIVE

This Standard Operating Procedure (SOP) defines the process used in the Indiana Clinical and Translational Sciences Institute (CTSI) Clinical and Translational Support Laboratory (CTSL) to maintain a safe and clean working environment. Also included are the procedures to ensure accurate timekeeping for the processing of samples and to maintain an acceptable temperature environment within the lab for the storage of ambient samples and reagents.

2. SCOPE

The SOP applies to CTSL personnel performing routine monitoring and recording of general maintenance procedures within CTSL managed laboratory spaces that include cleaning, time accuracy and temperature monitoring.

3. RESPONSIBILITIES

Designated staff is responsible for cleaning, time accuracy and temperature monitoring in all CTSL supervised labs.

4. DEFINITIONS

4.1. Principle: Routine monitoring and maintenance of work areas is important to minimize risk of the environmental failures causing or contributing to equipment failures within the facility, to document ambient storage conditions for specimens and reagents, for quickly detecting out of specification (OOS) conditions for synchronization of time with the Clinical Research Center to ensure accurate timekeeping during processing and maintaining a clean and safe work environment.

CRC: Clinical Research Center	CTSI: Clinical and Translational Sciences Institute
CTSL: Clinical and Translational Support Laboratory	HVAC: heating, ventilation and air conditioning
NIST: National Institute of Standards and Technology	OOS: Out of Specification
PL: Processing Lab	SOP: Standard Operating Procedure

5. ASSOCIATED DOCUMENTS

5.1. CTSI-CRC-QA-003 Document Control and Management



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- 5.2. CTSI-CRC-CLN-030 Handling of SOP Deviations
- 5.3. CTSI-CRC-PL-121 General Safety
- 5.4. CTSI-CRC-PL-105 Out of Specification Condition and Notification Management
- 5.5. CTSI-CRC-PL-LG612 CRC Laboratory Maintenance Log
- 5.6. CTSI-CRC-PL-LG613 CTSL Laboratory Maintenance Log

6. PROCEDURE

6.1. Materials

- 6.1.1. PPE including lab coat, gloves and eye protection
- 6.1.2. NIST-traceable thermometer per CTSI CRC PL 306 Thermometers
- 6.1.3. Access to www.time.gov website
- 6.1.4. Dispatch, 10% bleach solution or other approved cleaner

6.2. Record completion of all lab specific duties as listed on the appropriate Laboratory Maintenance Log (CTSI-CRC-PL-LG612 and CTSI-CRC-PL-LG613)

- 6.2.1. Laboratory Maintenance Logs may be modified as to block out weekends and holidays.
- 6.2.2. Place checkmarks on the lines of each completed duty and place performing technician's initials on each day /time of day of completion.
- 6.2.3. Management will review and enter signature and date of review after the month of record has ended.

6.3. Daily Temperature Checks

- 6.3.1. Read and record the hi-low and current readings at least once each work day from the digital thermometer in each CTSL supervised laboratory.
- 6.3.2. Acceptable Room Temperature Range: 18-25°C
 - 6.3.2.1. If within acceptable range, record, date and initial on the CTSI-CRC-PL-LG601 Work Area Daily Temperature Monitoring Log. High and Low values are informational only.
 - 6.3.2.2. If outside of acceptable range:
 - 6.3.2.2.1. If temperature exceeds the acceptable range, record and notify CTSL Management.
 - 6.3.2.2.2. If deemed necessary, document OOS per CTSI-CRC-PL-105 Out of Specification Condition and Notification Management and contact campus facilities to adjust HVAC settings.
 - 6.3.2.2.3. Record actions and results on CTSI-CRC-PL-LG601 Work Area Daily Temperature Monitoring Log.

6.4. Daily Refrigerator/Freezer Temperature Checks

- 6.4.1. Perform and record checks according to CTSI_CRC_PL-301 Mechanical Refrigeration Units.



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6.4.2. Refer to CTSI-CRC-PL-105 Out of Specification Condition and Notification Management if any temperature is out of range defined by CTSI-CRC-PL-301 Mechanical Refrigeration Units.

6.5. Check/Reset Clock

6.5.1. The clock(s) located in the CTSL will be checked for accuracy each work day.

6.5.2. Refer to www.time.gov for accurate time.

6.5.3. If there is a greater than 30 second difference between the lab clock and the www.time.gov standard, reset the clock to the correct time.

6.6. Clean Countertops/Sinks

6.6.1. Use only acceptable disinfectants such as dispatch or 10% bleach solution for cleaning countertops and sinks.

6.6.2. Keep surfaces wet with disinfectant for a minimum of 2 minutes or as required by manufacturer.

6.7. Clean Centrifuge Compartment and Buckets

6.7.1. Remove buckets and inserts from centrifuge when cleaning

6.7.2. Use approved cleaning solutions only - dispatch or 10% bleach solution along with a detergent are acceptable

6.7.3. Pay attention when returning buckets to rotors to be sure balance is maintained.

7. REFERENCES

7.1. NIST certification document received with thermometers

8. APPENDICES

None

9. AMENDMENT HISTORY

Date of Amendment: 08 Dec 2016

Amendment Request by: Robert Orr

Change Control No, if applicable: CTSI-CRC-PL-DC-2016-003

Details of Amendment: Updated to footer file location; Updated SOP reference in section 5.4 and 6.4.2; Removed section 6.5 concerning Accucheck control procedure (not done by CTSL); added clarity to section 6.7.