

	ORA LABORATORY PROCEDURE Food and Drug Administration	Document No.: ORA-LAB. 5.5	Version No.: 1.8
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Title: ATTACHMENT A		Effective Date: 10-01-03 Revised: 05-02-14	

Table 1. Equipment Maintenance and Performance Requirements

NOTE 1: Documentation is required for annual maintenance. NOTE 2: Daily refers to measurements when in use.

Equipment	Requirement	Minimum Frequency
Autoclaves	1. Clean 2. Temperature and Time 3. Sterile control all media 4. Spore vials or strips 5. Service	1. After spills 2. Daily 3. Each load 4. Weekly 5. As per manufacturer or laboratory procedure
Balances	1. Clean 2. Mass measurement 3. Service Note: Balances used for USP analysis meets compendial specifications.	1. After each use 2. Daily with internal calibration or with a reference weight 3. Annually
Centrifuges	1. Clean 2. Sanitize (for micro use) 3. Service	1. After spills or breakages 2. Each month 3. As per laboratory procedure
Chromatographs	1. Refer to instrument manufacturer's instructions	1. As recommended by manufacturer or per laboratory procedure
Freezers	1. Clean, sanitize and reorganize 2. Temperature	1. As scheduled by lab 2. Daily
Fume hoods	1. Clean 2. Air flow monitor 3. Service (to include airflow)	1. After spills 2. Quarterly 3. Annually
Heat Blocks (eg. VIDAS)	1. Temperature	1. Annually
ID Systems (eg. Vitek, VIDAS)	1. \pm Reaction each lot	1. \pm Culture reference
Incubators	1. Clean, sanitize 2. Temperature	1. As scheduled by lab 2. Daily am and pm
Media, prepared	1. Sterility, growth promotion, pH, appearance, expected reaction	1. Each batch
Microscopes	1. Clean objectives and eyepieces 2. Service	1. After each use 2. Annually
Ovens, Furnaces	1. Clean 2. Temperature	1. As scheduled by lab 2. Daily
Pipettes, petri dishes, plasticware (micro.)	Sterility	Each lot (manufacturer's certification fulfills requirement)
Rapid test kits (micro.)	Test in-house kit +/- controls.	Each lot and test run



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Refrigerators	1. Clean and sanitize 2. Temperature	1. As scheduled by lab 2. Daily
Still/De-ionized Water Systems	Clean DI System: Replace cartridge Service	As recommended by manufacturer
Safety Cabinets and Laminar flow hoods	1. Clean, sanitize 2. Test for air purity by exposing open culture plate 3. Service: check filter integrity, air flow velocity and direction 4. Monitor air flow	1. Each use 2. Each sample set-up 3. Annually 4. Quarterly
Spectrophotometers and Spectrometers (AA, UV/Vis fluorometric, ICP, Mass etc.)	1. Clean 2. System response (blank, standard, control, etc.)	1. After each use 2. Daily
Test reagents (micro)	1. +/- reaction	1. Each lot
Vial fillers (micro)	1. Clean	1. As scheduled by lab
Water, DI or Distilled	1. Conductivity 2. Aerobic Plate Count, Toxicity, Heavy Metals	1. Weekly 2. At installation, after repair, or system failure
Water baths	1. Clean 2. Temperature	1. As scheduled 2. Daily
pH meter	1. Clean electrodes	Each use