

Flexible Scopes

Life Sciences Advisory Committee

April 4, 2009

DRAFT
SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

DHHS/ORA/FDA
PACIFIC REGIONAL LABORATORY NORTHWEST
22201 23rd Drive SE
Bothell, Washington 98021
Marilyn G. Chase Phone: 425 402 3175

CHEMICAL

Valid to: May 31, 20__
2318.02

Certificate Number:

In recognition of the successful completion of the A2LA evaluation process (including an assessment of the laboratory's compliance with the A2LA Food Testing Program Requirements containing the “*AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals*”), accreditation is granted to this laboratory to perform the following tests on drugs and food additives:
Pharmaceuticals for Assay, Identification, Dissolution, and Release

Spectroscopy:

FTIR
UV/Visible

Chromatography:

Gas Chromatography
Gas Chromatography/Mass Spectrometry
High Performance Liquid Chromatography
Liquid Chromatography/Mass Spectrometry
Thin Layer Chromatography

Wet Chemistry:

Titration (Karl Fisher Automated)
Selected Ion Electrode

By methods such as:

FDA (LIBs), Drug Applications: New & Abbreviated (NDA & ANDA), United States Pharmacopeia (USP-NF), European Pharmacopeia and Japanese Pharmacopeia. A variety of methods are used and compounds analyzed may not be routine. Drug company methods that are proprietary also called FIRMS “methods” are used.

Accreditation is granted to this laboratory to perform the following tests on human foods of animal and plant origin for isolating, identifying and quantifying pesticides, drug residues and toxins in animal tissues, animal feeds and food by:

Spectroscopy:

- Fluorometric
- UV/Visible

Chromatography:

- Gas Chromatography
- Gas Chromatography/Mass Spectrometry
- High Performance Liquid Chromatography
- High Performance Liquid Chromatography / Triple Quad Mass Spectrometry

Wet Chemistry:

- Titrimetric

Using the following method references:

- Official Methods of Analysis of the AOAC International
- Journal of the Association of Official Analytical Chemists (JAOAC)
- FDA Laboratory Information Bulletins (LIB)
- Pesticide Analytical Manual (PAM)
- FDA Compliance Programs Guides

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A & P GROWERS
26487 North Highway 99
Tulare, CA 93274
Kristine Johnson Phone: 559 685 3663

BIOLOGICAL

Valid to: November 30, 2009

Certificate Number: 2539.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on almonds and pistachios:

<u>Test</u>	<u>A & P SOP No.</u>
<u>Quantitative Microbiology</u>	
Aerobic Plate Counts	056
Presence of Coagulase-Positive <i>Staphylococci</i>	055
Presence of <i>Escherichia coli</i>	054
Yeast and Mold Counts	057
<u>Qualitative Microbiology</u>	
Presence of <i>Salmonella</i> spp.	110

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BIOLOGICAL? CHEMICAL?

Valid To: Month xx, 20--

Certificate Number: XXXX.XX

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests to identify the presence or absence of biothreat agents in potentially contaminated (unknown) samples in a liquid buffer matrix.

Test Type:

Method

Qualitative Real Time PCR

IOPx, IOPxx, IOPxxx, IOPxxxx,

Bacillus anthracis

Yersinia pestis

Francisella tularensis

Orthopox/Variola virus

Qualitative ECL

IOPy, IOPyy, IOPyyy, IOPyyyy

Bacillus anthracis

Yersinia pestis

Francisella tularensis

Orthopox/Variola virus

Botulinum Toxin

Ricin

SEB