Typical findings from ISO/IEC 17025 Assessments

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PJLA, Technical & Intl. Business Development Manager

About PJLA

Perry Johnson Laboratory Accreditation, Inc. (PJLA)

Established in 1999 by Mr. Perry L. Johnson

Headquartered in Troy, Michigan.

More than 2200 accreditations globally in 32 countries.

Perry L. Johnson

Perry Johnson Laboratory Accreditation NP, Inc. (PJLANP)
Michigan nonprofit organization established in 2016.

Member and signatory of APAC, ILAC MRAs

PJLA's Global Network

PJLA Accreditation Programs

ISO/IEC 17025

Testing/Calibration Labs

- FCC OET Equipment Authorization
- FDA ASCA
- ENERGY STAR
- Cannabis Testing
- Hemp Testing
- Horseracing Laboratories Program
- CPSC
- AS6171A Testing
- Food, Feeds, and Pharmaceutical: *AOAC, AAFCO, LAAF*
- Environmental Testing: *TNI-NEFAP, DoD ELAP, DOECAP-AP, EPA NLLAP*
  TNI-EL: *MNELAP, CA ELAP, LELAP*

ISO/IEC 17020 – Inspection Bodies

ISO/IEC 17065 – Product Certification Bodies

ISO/IEC 17043 – Proficiency Testing Providers

ISO 17034 – Reference Material Producers

ISO 15189 – Medical Laboratories

ISO/IEC 17024 – Personnel Certification Bodies

ASTM E2659– Training Providers

Contents

Typical Findings:

- Risk Assessment related issues
- Technical issues
- UoM issues
- Management System issues

Main Improvement Opportunities

Risk Assessment related issues

- Lack of understanding of risk related Impartiality requirements

  4.1.4 The laboratory shall identify risks to its impartiality on an on-going basis.
  4.1.5 If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.

- General risks

  8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities
  8.5.2 The laboratory shall plan actions to address these risks and opportunities

Technical issues

- Equipment calibration and maintenance (6.5.2)
- Non-standard test methods – validation (7.2.2)
- Monitoring and updating employees on new testing methodologies (7.2.1.6)
- Ensuring the validity of test results (7.7) – procedure required
- No evidence of assuring the quality of all test results (7.7.2 PT/Interlaboratory comparisons)
- No evidence of intermediate controls/checks (7.7.1e)

UoM issues

- Uncertainty of Measurement (7.6) not calculated (confusion between testing lab and calibration lab requirements)
- Using “fixed” only UoM
- Mistakes in estimation of UoM – missing parameters
  - ***Type A*** *Uncertainty: Evaluated by statistical analysis of repeated observations.*
  - ***Type B*** *Uncertainty: Evaluated from sources other than statistical analysis, such as information about the instrument or environmental conditions.*
- Laboratory key personnel does not understand Uncertainty of Measurement mechanics (usage of IT)

Management System Issues

- Internal audits (8.8)
- Not auditing your processes

  6.2.1 All personnel of the laboratory… shall act impartially
- Lack of root cause analysis

  8.7.1b determining the causes of the nonconformity
- Management review (8.9)
- Lack of addressing key requirements and topics during Management Review (8.9.2)

Main Improvement Opportunities (1/2)

- Develop and maintain a comprehensive QMS with clear policies, work instructions, and records, as required.
- Regular internal audits and management reviews should be conducted to ensure compliance with ISO/IEC 17025.
- Establish a structured training program with regular competency assessments for all staff. Ensure staff are updated on new procedures or standards.
- Ensure that all instruments are calibrated, maintained, and traceable to international standards.

Main Improvement Opportunities (2/2)

- Regular evaluation of equipment performance and documentation of maintenance activities are critical.
- Adopt risk-based thinking to identify and mitigate potential issues before they impact operations.
- Foster a culture of continuous improvement through regular training, process optimization, and performance monitoring.
- Create a corrective action log to track nonconformities, root causes, and resolutions, ensuring they are addressed before the next audit cycle.

Additional Considerations

- **Cost and Resource Challenges:** Accreditation often requires significant investment in equipment, training, and consultation, which can strain resources. Laboratories should plan budgets and prioritize improvements based on risk considerations and audit findings.
- **Global Recognition:** PJLA accreditation to standards like ISO/IEC 17025, through APAC and ILAC MLA, enhances global acceptance of results, but laboratories must maintain compliance to all applicable PJLA and other applicable Policies. (https://www.pjlabs.com/resources/technical-resources)
- **Collaboration with PJLA:** Maintaining open communication with PJLA, can provide guidance for addressing nonconformities and improving processes.

Roadmap to Accreditation

Expression of Interest

Non-binding Application - Quotation

Agreement

Pre-Assessment

Assessment

Accreditation

Surveillance

Re-Assessment

Roadmap to Accreditation

PERRY JOHNSON LABORATORY ACCREDITATION, INC.

Certificate of Accreditation

Perry Johnson Laboratory Accreditation, Inc. has assessed the Laboratory of:

General Inspectors Inc.
1600 South Jackson Street, Seattle, WA 98144

(Hereinafter called the Organization) and hereby declares that Organization is accredited in accordance with the recognized International Standard:

ISO/IEC 17020:2012

This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (as outlined by the joint ISO-ILAC-IAF Communique dated January 2009):

Food Testing
(As detailed in the supplement)

Accreditation claims for such testing and/or calibration services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.

For PJLA:

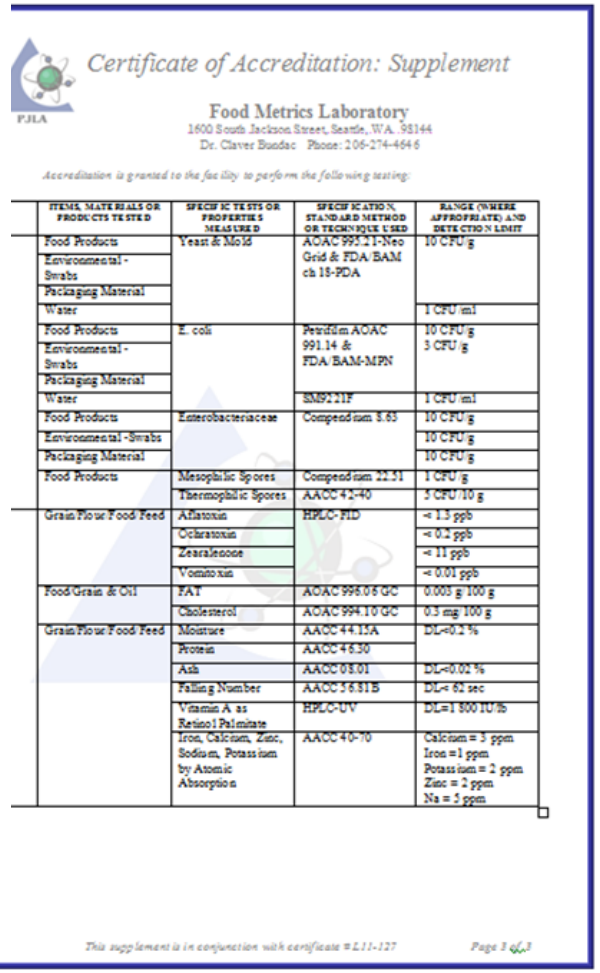
Initial Accreditation Date:	Issue Date:	Accreditation No.:	Certificate No.:
March 30, 2012	March 30, 2012	99999	L12-00

Tracy Szerszen
President/Operations Manager

Perry Johnson Laboratory Accreditation, Inc. (PJLA)
755 W. Big Beaver, Suite 1325
Troy, Michigan 48084

The validity of this certificate is maintained through ongoing assessments based on a continuous accreditation cycle. The validity of this certificate should be confirmed through the PJLA website: www.pjlabs.com

Page 1 of 3



Certificate of Accreditation: Supplement

Food Metrics Laboratory
1600 South Jackson Street, Seattle, WA 98144
Dr. Claver Bundac Phone: 206-274-4646

Accreditation is granted to the facility to perform the following testing:

ITEMS, MATERIALS OR PRODUCTS TESTED	SPECIFIC TESTS OR PROPERTIES MEASURED	SPECIFICATION, STANDARD METHOD OR TECHNIQUE USED	RANGE (WHERE APPROPRIATE) AND DETECTION LIMIT
Food Products	Yeast & Mold	AOAC 997.21-Neo Grid & FDA/BAM ch 18-PDA	10 CFU/g
Environmental - Swabs			
Packaging Material			
Water			1 CFU/ml
Food Products	E. coli	Petrifilm AOAC 991.14 & FDA/BAM-MPN	10 CFU/g 3 CFU/g
Environmental - Swabs			
Packaging Material			
Water		SM9221F	1 CFU/ml
Food Products	Enterobacteriaceae	Compendium 5.63	10 CFU/g
Environmental - Swabs			10 CFU/g
Packaging Material			10 CFU/g
Food Products	Mesophilic Spores	Compendium 22.51	1 CFU/g
	Thermophilic Spores	AACC 42-40	5 CFU/10 g
Grain/Flour/Food/Feed	Aflatoxin	HPLC-FID	< 1.3 ppb
	Ochratoxin		< 0.2 ppb
	Zearalenone		< 11 ppb
	Vomitoxin		< 0.01 ppb
Food/Grain & Oil	FAT	AOAC 996.06 GC	0.003 g/100 g
	Cholesterol	AOAC 994.10 GC	0.3 mg/100 g
Grain/Flour/Food/Feed	Moisture	AACC 44-15A	DL<0.2 %
	Protein	AACC 46-30	
	Ash	AACC 08-01	DL<0.02 %
	Falling Number	AACC 56-81B	DL< 62 sec
	Vitamin A as Retinol Palmitate	HPLC-UV	DL=1 800 IU/lb
	Iron, Calcium, Zinc, Sodium, Potassium by Atomic Absorption	AACC 40-70	Calcium = 5 ppm Iron = 1 ppm Potassium = 2 ppm Zinc = 2 ppm Na = 5 ppm

Issued: 9/11 *This supplement is in conjunction with certificate # L11-127* Page 3 of 3

PJLA
Inspection
Accreditation #12345

Thank You!

- Questions
- Discussion

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