# Accreditation Insider

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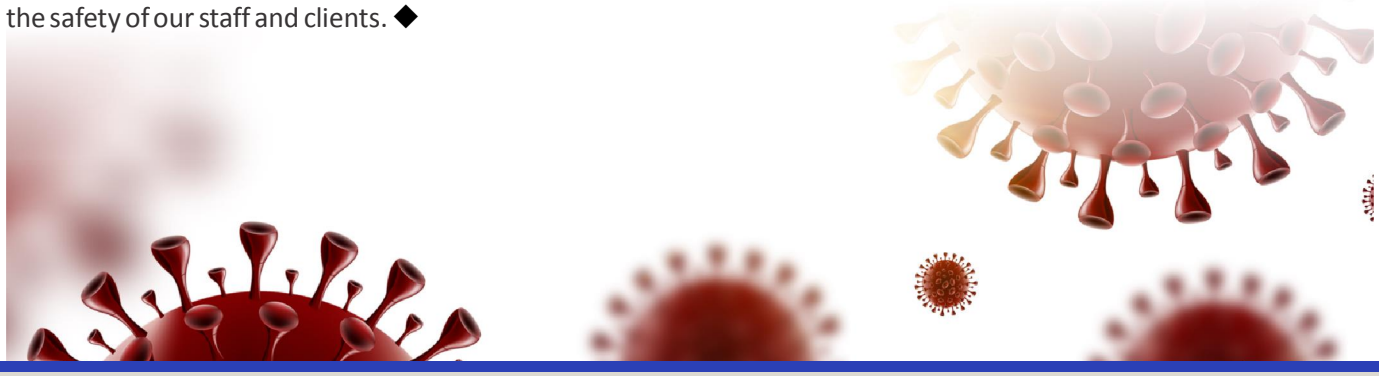
## PJLA COVID Update

Based on the existing COVID-19 cases rising within the United States and across the world, PJLA will continue to allow virtual remote assessments until the 1st quarter 2021. In some cases, we will conduct on-site assessments based on client request, regulatory requirements, unique or high sophisticated testing, or at labs that do not have the capability to perform their assessment remotely.

We have developed protocols to monitor our assessors performing on-site assessments and have asked all clients to sign a COVID-19 wavier stating that they follow CDC guidelines. We are hoping after the 1st quarter 2021 our comfort level will improve with on-site assessments, but we will continue to monitor the situation to ensure the safety of our staff and clients. ◆



## Update To The CA ELAP

PJLA has conducted our first laboratory accreditation assessment in support of the California ELAP initiative to utilize third-party assessment bodies. This assessment was conducted to the full TNI EL 2016 standard and the CA Regulations which will be accepted by the state upon receipt of the report and recommendation letter. We anticipate several more assessments as we move into 2021, especially with the stipulation for labs with high sophisticated techniques to use third-party assessment bodies like PJLA to conduct their assessment to satisfy their 2022 application requirements. We are excited to be part of this program and to finally see the benefits of becoming a TNI Non-Governmental Accreditation Body. ◆

## ISO/IEC 17025:2017 Transition Extended Until June 1, 2021

Due to the ongoing pandemic, ILAC has agreed to allow the accreditation bodies an additional 6 months to transition their laboratories to the new ISO/IEC 17025:2017 standard. As written in prior notifications, laboratories were previously required to have an assessment by August 2020 to meet the November 2020 transition deadline. We do still expect the laboratories that have already committed to an earlier date to continue with this date. The new extended timeline is for severe circumstances where laboratories could not fully operate, making it impossible for an assessment of any type to occur. Laboratories that fall into this situation must complete their assessment by **February 28, 2021** to meet the June 1, 2021 extended transition deadline. ◆

## IN THIS ISSUE:




**Perry Johnson Laboratory Accreditation, Inc.**

**World Headquarters**
755 W. Big Beaver, Suite 1325
Troy, Michigan 48084

**Phone:**
1-877-369-5227 or
(248) 519-2603

**Email:**
pjlabs@pjlabs.com

**Website:**
www.pjlabs.com

**Publisher:**
Tracy Szerszen

**Editor:**
Tracy Szerszen • Tami Carr

**Writer:**
Tracy Szerszen • Kristen Hogerheide
Stone Zhang

**Layout & Design:**
Jason Millbrand




# New PJLA Patents

## A Big Thank You to Yoshio Kunitomi for his Support!

PJLA's Japan Director of Operations, Mr. Yoshio Kunitomi has assisted PJLA to develop patents for various testing techniques within the Thermodynamic, Mechanical and Biological Fields.

- Soaking Copper Blocks to Improve the Wide Precision Range found when performing Temperature Calibration
- Simulated Blocks for Vibration Tests of Packaged Freight- To reduce cross-talk caused by the natural vibration of tables
- Development of an alternative method for measurement uncertainty when performing Sensory Testing utilizing matrix reduction tables

Yoshio Kunitomi

These methodologies were developed with the support of some of PJLA's accredited laboratories in Japan and are being now being utilized in the market.

Yoshio Kunitomi is the Director of Operations, of Perry Johnson Laboratory Accreditation, Inc.'s Japan office branch with decades of successful experience within the industry. ◆

# PJLA Would Like To Welcome Our New Team Members!

**Tish Lee**
Accreditation
Program Assistant

**Melissa Chahine**
Accreditation
Program Assistant

**Courtney Leder**
Accreditation
Program Assistant

**Madeline Perraut**
Administrative
Assistant

# *Client Spotlight: Cannabis Testing Laboratory (CTL)*

**Perry Johnson Laboratory Accreditation Inc. is happy to introduce Cannabis Testing Laboratory (CTL), an ISO/IEC 17025 accredited testing laboratory that is a subsidiary of Doane University.**

CTL currently the FIRST iso-accredited and state approved testing facility in the state of Nebraska. The founders Arin Sutlief and Andrea Holmes recognized the need for their lab right away when it became clear that there were no in-state accredited testing labs.

**"The [ISO/IEC 17025:2017] accreditation instantly brought credibility to our lab."**
**Dr. Jacque Carter, Doane's President**

**www.ctlcrete.com** **402-826-8325**



CTL has a team of Senior PhD organic chemists and offers a variety of testing services for the cannabis and hemp communities including potency testing with High Performance Liquid Chromatography (HPLC), as well as Nuclear Magnetic Resonance (NMR) for clients who want to further characterize isolated samples. Additional characterizations include comprehensive potency testing, analysis of the presence of pesticides, residual solvents, microbiological contaminants, mycotoxins, heavy metals, terpenes, water activity, moisture content, and filth/foreign material testing.

Accreditation with PJLA helped CTL immediately receive state approval, which led them to be the first state-approved cannabis testing site, a notable achievement that has led to positive brand recognition. Potential clients are now checking to see that testing methods are being validated and seek out testing facilities with legitimacy and experience. Each day, the focus on safety and compliance in the products customers are purchasing is becoming more important. Starting with a testing laboratory that has ISO/IEC 17025 reinforces these credentials and makes consumers feel safe.

"Working with PJLA was a life saver for CTL. PJLA listened to our concerns that we were under severe time constraints and external pressure to get accredited. PJLA rolled up their sleeves and went to work with us. They guided us through the process every step of the way starting from the first phone call all the way until we received our certificate. The Accreditation is the stamp of approval, the seal of competence, and the mark of trusted results."

Moving forward, CTL has plans to become the leader in analytical and microbial testing of cannabis in the Midwest and beyond. Their first steps to expanding their influence involves educating cultivators, farmers, brokers, and the general public & eventually opening more testing facilities. ◆

## *Conferences*

**Virtual VOXPO – Vape Live/CBD Live**
November 18-20, 2020 | 10:00am - 6:00pm
PJLA's Brett McMillen will be presenting.

**Cannabis Quality Virtual Conference Series Event**
November 17, 2020 | 12:00pm - 2:30pm
Tracy Szerszen, PJLA President, will be presenting during the Laboratory Accreditation Panel Discussion

# PJLA Has Now Been Approved As An FDA ASCA Accreditation Body

On September 25, 2020, the FDA issued three final guidance documents to support their Pilot Program for Medical Device Testing Laboratories and Accreditation Bodies. PJLA has recently been selected as one of the first five FDA ASCA accredited Accreditation Bodies for this program.

This includes the following documents:

ASCA Pilot program guidance: The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Final Guidance

Basic Safety and Essential Performance standards-specific guidance: Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

Biocompatibility standards-specific guidance: Biocompatibility Testing of Medical Devices- Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program.

Although, this program is voluntary for laboratories it provides them a market advantage and demonstrates their ability to go above and beyond the ISO/IEC 17025 standard. In order for laboratories to be part of the ASCA approved laboratory listing, they must utilize an accreditation body approved by the FDA to conduct their assessment to ISO/IEC 17025 and to the ASCA requirements. Laboratories must be accredited to perform test methods as outlined in either or both guidance documents **Basic Safety and Essential Performance Standards** and **Biocompatibility Standards**.

Please visit the FDA site to seek more information about this program at: https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca .

Laboratories interested in this accreditation are encouraged to contact PJLA for more information! ◆

# PJLA Update Notifications

**Attention All Applicant and Accredited CABs:**

The latest PJLA Update Notifications are listed below. To download the latest revisions of these documents please visit the PJLA Documents section of our website.

**Update Notification #49**
Environmental DoD, DOECAP, TNI and state CABs
Update Notification Release Date: 10/26/20
Form/Procedure/Policy(s):
LF-56 TNI 2016 Work Document Rev 1.0 (New)
LF-56 DoD, DOE, TNI Working Document 5.3 Rev 1.8

**Update Notification #50**
AOAC Working Document Upgrade to 2017
Update Notification Release Date: 10/26/20
Form/Procedure/Policy(s):
LF-56 -2k17 AOAC Working Documents Rev 1.0 (New)

**Update Notification #51**
Update Notification Release Date: 10/26/2020
Form/Procedure/Policy(s):
SOP-1 Accreditation Procedure
SOP-3 Use of Accreditation Claims and Symbols Procedure
SOP-9-Complaint Procedure
SOP10-Dispute and Appeal Procedure
SOP-11-Suspension, Withdrawal and Reduction of Accreditation Procedure

If you have any questions or need clarification on any of these changes, please call our office at 1-877-369-5227 or (248) 519-2603 or email us at pjlabs@pjlabs.com.◆

# *PJLA Accredits Quality World To ISO 15189 For COVID Testing*

Quality World is a clinical laboratory located in Zapopan, JA. They are a laboratory of German origin merged with a Mexican laboratory. Thanks to this alliance, they have a goal of creating a link between the industries of Latin America and Europe.

Congratulations to Quality World for becoming ISO 15189 accredited for their SARS-CoV-2 Real Time PCR testing. The collection type for SARS-CoV-2 testing at Quality World is Nasopharyngeal, but they also complete several other types of collection: Oropharyngeal aspirate and surface swabs using RNA extraction. Meaning, this testing is conducted using RNA extraction to test for the presence of antibodies created as a defense to the COVID-19 virus. Quality World currently releases results within 48 hours.

The lab has a very professional team who consist of a quality director, Fabiola Báez (who was swabbed and tested for COVID during their assessment) and a technical team who specialize in technical SOP and procedure creation to support their methodology and validation.

To the left is an example of what the lab technicians look like in their PPE. They wear this for the entire process - from collection to running the sample under a protected hood. ◆

**"The lab was excellently prepared for their 2-day assessment and did not receive any areas of nonconformance."**

*– Kelli Ramos, Medical Technical Program Manager*

## *Client Spotlight: PSI Labs*

We are happy to introduce PSI Labs, an ISO/IEC 17025 accredited testing laboratory located in Ann Arbor, Michigan. PSI Labs is one of Michigan's first licensed and ISO accredited cannabis testing laboratories and has consistently set the benchmark for consumer and business advocacy, product quality control, and above all else, scientific integrity.

We recently got the opportunity to visit PSI Labs to speak with Frank Barretta, their Director of Quality & Compliance. Check out our feature video at: www.youtube.com/watch?v=Fhm6tuS-Jb0. ◆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## *Look Out For PJLA's FREE Online Webinars!*

For our full schedule and to register for upcoming webinars visit our website at www.pjlabs.com/training/pjla-webinars.

- **Monday, November 23 – 1:00pm EST**
  **ISO/IEC 17025:2017 and Section 8.8 on Internal Audits**
- **Wednesday, December 30 – 1:00pm EST**
  **ISO/IEC 17025:2017 -7.6 & 7.7 -Evaluation of Measurement Uncertainty & Validity of Results**

***Testimonial:***

*"I have been attending these webinars offered for various sections of new ISO/IEC 17025:2017 standards. I enjoy the presentations and the contents have been very useful and applicable for me who work in the Quality Assurance Section of our laboratory. I have a direct involvement with our laboratory Quality System (QS) including creating and updating of our Quality Manual, performing internal audits, and providing QS trainings as examples of some of the related tasks.*

*I also would like to take this opportunity and thank Mr. Kramer for the great job he does in creating and presenting these webinars. The availability of the webinars for future access are a very useful resource to use for future reference, refresher to learn more about each topic, etc."*

**Fathieh Shafiee**
*Program and Policy Analyst*
*Advanced Quality Assurance Section Bureau of Laboratory Services/Division of Management Services*
*Wisconsin Department of Agriculture, Trade and Consumer Protection*