INFORMATION ON LABORATORY LICENSING AND QUALITY CONTROL PROCEDURES

Our Mission

Lifeline Diag provides precise and reliable Elemental Hair Analysis (EHA), offering our clients and partners top-quality diagnostic data based on modern technologies, standardized procedures, and a team of experts with international experience.

Analytical and Technological Standards

- ICP-OES technique (Avio 200, PerkinElmer) as the primary method for trace element determination.
- Sample mineralization using concentrated nitric acid (HNO_3) under strictly controlled conditions.
- Result registration and processing in an IT system ensuring full traceability
of each sample.
- Implementation of Clean Zone Workflows – separate areas for preparation, mineralization, and analysis, with contamination and temperature control.

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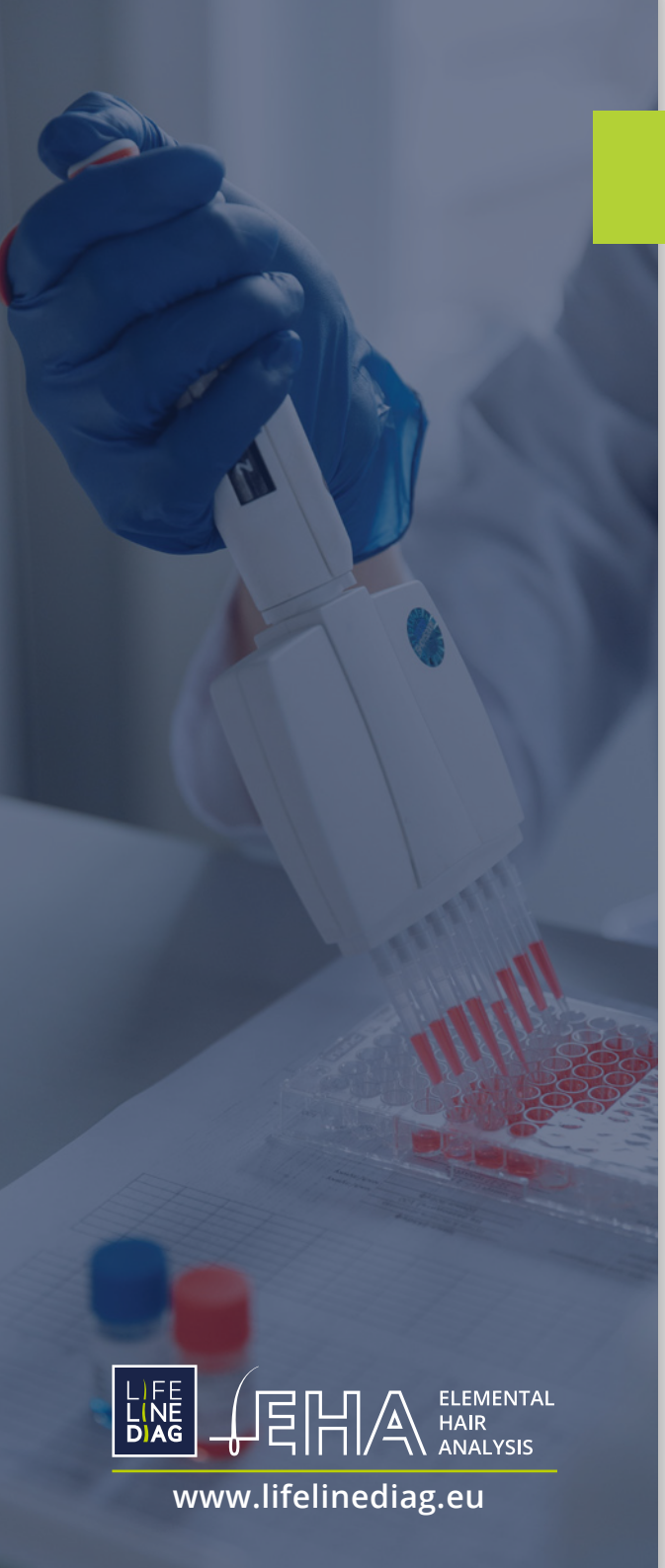

Calibration, Control, and Validation of Results

- Daily calibration of equipment using NIST-traceable standards.
- Use of certified reference materials (CRMs) in each analytical batch.
- Split and control samples analyzed in each series to verify repeatability and precision.
- Use of internally developed calibration curves with traceable origin, updated for each analytical run.
- Validation of analytical series every 24 samples.
- No acceptance of results if any control point falls outside defined quality control (QC) limits.

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Laboratory Environment and Working Conditions

- Laboratory equipped with workstations with controlled ventilation and HEPA filtration at critical stages of sample preparation.
- Clean areas (Clean Bench/Room) separating the mineralization stage from spectrometric analysis.
- All glass and plastic labware are acid-leached, triple-rinsed, and dried in controlled conditions.

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Reagents and Materials

- Ultra-pure grade analytical reagents (Suprapur).
- Water used in analysis: 18.2 MΩ/cm (ultrapure), obtained from a two-stage deionization system.
- Tubes and containers: medical/analytical grade, tested for trace element contamination before use.

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Internal QA/QC Procedures

- Daily analysis of a pooled hair control sample (PHCM), a split sample from the previous day, and a CRM-H sample.
- Routine analysis of spiked samples to assess element recovery rates.
- Trend analysis of patient data in the LIMS system – identifying anomalies and initiating QA intervention if needed.
- Automated Quality Control (AQC) system supporting validation of results before release.

Personnel and Scientific Oversight

- All processes are supervised by the Chief Analyst and Laboratory Manager.
- Technicians undergo regular internal training and quarterly practical audits.
- Additional training provided in cooperation with international partners and technology providers.

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Audits and Comparative Testing

- Regular quality system audits by external consultants or certification partners.
- Planned participation in proficiency testing programs in cooperation with European laboratories.
- Internal audits covering: discrepancy analysis, procedure validation, workplace safety, and reporting quality.

Documentation and Transparency

- Full audit trail for each sample – from receipt to report release.
- Archived results, calibration curves, and quality documentation available upon partner request.
- Reports include reference ranges developed from a „healthy” population database, adjusted for gender and age, and based on international data.

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Near-Term Objectives (Strategic Option)

- Participation in interlaboratory comparison studies with European partners.

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Quality Assurance as a Core Value

At LifelineDiag, we believe that analytical reliability is the foundation of diagnostics and client trust. That is why we continuously invest in cutting-edge technology, personnel development, and the refinement of our QA/QC procedures.

Marcin Maciąg
CEO
LifelineDiag Sp. z o.o.

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