

SITI NURFAUZIANA

Analytical Development | Method Verification & Validation | Stability Testing | Laboratory Quality

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Jakarta, Indonesia

Biology graduate from Institut Teknologi Bandung with nearly 2 years of hands-on R&D, Quality Control, verification/validation, stability-testing, and regulated-laboratory experience in the IVD medical-device industry. Supported 5 product programs from development through validation and commercialization, including external validation of TB and Malaria diagnostics using 100 positive and 100 negative samples per project and accelerated/transport stability studies for an HPV PCR kit. Experienced in sample and reagent preparation, pH measurement, controlled testing, comparative analysis, result review, repeat testing, root-cause investigation, specification-based acceptance, and technical reporting. Maintain 40+ CoA/batch-QC records and controlled validation/stability documentation with strong data traceability. Skilled in Microsoft Excel, GraphPad Prism, RStudio, Python, MATLAB, SOP-controlled workflows, cross-functional coordination, and structured analytical problem solving.

LinkedIn



WhatsApp



Work Experiences

PT Bestari Sukses Makmur — Jakarta, Indonesia

Oct 2024 - Present

Research and Development Specialist

- Support 5 IVD product programs through analytical testing, verification/validation, stability studies, and commercialization.
- Prepare test plans, samples, controls, reagents, equipment, acceptance criteria, and traceable records for evaluations.
- Support external validation using 100 positive and 100 negative samples per project for TB and Malaria diagnostics.
- Perform comparative testing, repeat testing, stability evaluation, product-performance review, and troubleshooting.
- Review analytical and process results against predefined specifications and document deviations requiring follow-up.
- Evaluate raw materials, reagents, consumables, and process variables using controlled comparative testing.
- Support pH measurement, PCR/qPCR workflows, automated extraction, centrifugation, and ELISA-based equipment operation.
- Investigate unexpected results through evidence review, root-cause analysis, parameter changes, and follow-up testing.
- Maintain validation/stability records, specifications, SOPs, batch records, trial logs, BOMs, and technical reports.
- Coordinate technical testing with QC, Quality, Regulatory Affairs, Production, laboratories, and overseas principals.
- Use Excel and scientific software to analyze results, compare performance, review trends, and support decisions.

PT Bestari Sukses Makmur — Jakarta, Indonesia

Oct 2024 - Present

Quality Control Staff (concurrent role)

- Perform incoming-material, in-process, packaging, finished-product, verification, and release-related QC activities.
- Maintain 40+ CoA/batch-QC records and review results against product specifications and acceptance criteria.
- Prepare samples, reagents, controls, consumables, and equipment for routine and investigative laboratory testing.
- Perform pH measurement, physical checks, controlled testing, and structured analytical-result verification.
- Identify atypical or non-conforming results and support repeat testing, technical investigation, and root-cause review.
- Support CAPA evidence, corrective actions, controlled-document updates, and closure tracking for quality findings.

PT ProSTEM — Jakarta, Indonesia

Jul 2024 - Sep 2024

Laboratory Intern - Molecular Biology

- Processed approximately 10-20 clinical samples per week using SOP-controlled laboratory workflows.
- Prepared samples/reagents and performed DNA/RNA extraction, PCR/qPCR, and routine manual liquid handling.
- Maintained sample traceability, testing records, result documentation, and routine equipment readiness.

Institut Teknologi Bandung (ITB) — Bandung, Indonesia

Jul 2023 - Oct 2024

Research Assistant & Data Analyst

- Supported experimental research involving 160+ structured interviews and controlled EEG data collection.
- Analyzed quantitative data using MATLAB, EEGLAB, RStudio, Python, and GraphPad Prism.
- Performed data-quality review, statistical interpretation, visualization, and structured technical reporting.

Bandung Fertility Center — Bandung, Indonesia

Jul 2023 - Aug 2023

Data Analyst & Laboratory Intern

- Performed sample preparation, centrifugation, microscopy, and CASA-based laboratory analysis.
- Analyzed reproductive-cell quality parameters for 35+ IVF patients and maintained accurate analytical records.

Education Level

Institut Teknologi Bandung — Bandung, Indonesia

Sep 2020 - Jul 2024

Bachelor of Biology, GPA 3.36

- **Achievement:** TELADAN Scholarship & Leadership Program Awardee by Tanoto Foundation
- **Thesis:** analyzed cognitive-test and EEG data from 35 students using quantitative experimental methods.
- **Head Laboratory Assistant:** led 12 TAs and coordinated 14 laboratory sessions for 70+ students.
- **Lab Assistant:** supported Basic Chemistry and Animal Anatomy & Physiology laboratory activities.
- **Relevant areas:** Biochemistry, Molecular Biology, Biotechnology, Laboratory Techniques, Statistics, Research Methods

Organization

Tanoto Scholars Association (TSA ITB) — Bandung, Indonesia

Jan 2021 - Jan 2023

Internal Affairs & Community Engagement

- Led engagement initiatives strengthening coordination across a community of 100+ scholars.
- Coordinated the Study Buddy mentoring program supporting 30+ elementary-school students.

Biology Student Association (HIMABIO ITB) — Bandung, Indonesia

Aug 2021 - Aug 2022

Treasurer

- Managed approximately Rp25,000,000 in organizational funds and maintained accurate financial records.
- Improved cash reserves by approximately 20-25% through budget control and resource allocation.

Selected Analytical Development, Validation & Stability Experience

• TB & Malaria Diagnostics - Method Verification/Validation & Reporting

- Support external validation using 100 positive and 100 negative samples per project under approved test plans.
- Prepare samples, controls, acceptance criteria, test records, comparative review, troubleshooting, and follow-up evidence.
- Maintain validation records and technical reports with complete sample, result, and document traceability.

• Best's 18 HPV PCR Kit - Stability & Analytical Performance Review

- Supported accelerated stability testing at 37°C ±3°C and repeated transport-temperature cycles.
- Review performance trends, acceptance criteria, deviations, repeat results, and required technical follow-up.

• Analytical Troubleshooting & Comparative Testing

- Investigate unexpected results using repeat testing, parameter review, evidence comparison, and root-cause analysis.
- Compare product/process variables and analytical performance to support controlled improvement decisions.

• Laboratory Equipment, pH Testing & Test Readiness

- Support pH measurement and readiness/operation of qPCR, extraction, centrifuge, ELISA, BSC/LAF, and autoclave systems.
- Maintain equipment-related test readiness, operating records, sample identification, and laboratory traceability.

• Controlled Analytical Documentation & Quality-System Support

- Maintain test plans, specifications, SOPs, batch records, validation/stability records, trial logs, and technical reports.
- Support ISO 13485, CAPA, risk-assessment, controlled-document, and audit-readiness activities.
- Coordinate testing and documentation with R&D, QC, Quality, RA, Production, laboratories, and principals.
- Use Microsoft Excel and scientific software for data review, trend analysis, comparative evaluation, and reporting.
- Maintain organized analytical evidence, action tracking, and complete data traceability across active workstreams.

Skills

• **Analytical Testing:** Sample/Reagent Preparation, pH Measurement, Controlled Testing, Result Review, Specification Comparison

• **Method Verification & Validation:** Test Plans, Controls, Acceptance Criteria, Comparative Review, Technical Reporting

• **Stability Studies:** Accelerated Stability, Transport Stability, Real-Time Support, Trend Review, Traceability

• **Analytical Troubleshooting:** Repeat Testing, Root-Cause Review, Parameter Evaluation, Corrective Follow-Up

• **Laboratory Systems:** pH Meter, qPCR, Automated Extraction, ELISA, Centrifuge, BSC/LAF, Autoclave

• **Controlled Documentation:** SOP, Specifications, Batch Records, Validation Records, Stability Records, Trial Logs

• **Quality Systems:** ISO 13485, CPAKB, CDAKB, CAPA Support, Risk Assessment Support, Audit Readiness

• **Data Analysis:** Microsoft Excel, GraphPad Prism, MATLAB, RStudio, Python, Comparative & Trend Analysis

• **Cross-Functional Coordination:** R&D, QC, Quality, Regulatory Affairs, Production, Laboratories, Principals

• **Professional Strengths:** Detail Orientation, Analytical Thinking, Responsibility, Communication, Organization, Teamwork