

Access Before Analysis™

Pre-Analytic Access Variability Framework

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|-----------------|---------------|-----------------|
| Device-Agnostic | Observational | Non-Comparative |
|-----------------|---------------|-----------------|

Objective

To characterize pre-analytic access variability in defined pediatric laboratory encounters before analytic evaluation or device performance comparison begins.

This framework does not evaluate analyte correlation, device performance, or clinical outcomes. It examines whether the conditions necessary for analytic evaluation reliably exist within developmentally variable pediatric environments.

Access feasibility precedes analytic interpretation.

Rationale

Analytic validation assumes that a specimen can be obtained for comparison. In pediatric settings, particularly within developmentally variable outpatient encounters, this assumption does not consistently hold.

When specimen acquisition fails, is delayed, or is abandoned:

- No analytic comparison is possible
- Performance metrics exclude the encounter
- High-variability patients disappear from structured evaluation

Unmeasured access variability creates a structural blind spot in pediatric diagnostics and workflow assessment. Access Before Analysis™ formalizes structured observation of this upstream layer — without entering analytic, comparative, or regulatory domains.

This is not a study of devices. It is a structured characterization of whether evaluative conditions exist at all.

Core Domains

The framework operationalizes three pre-analytic domains:

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|--|---|--|
| <p>Access Readiness</p> <p><i>Developmental and environmental conditions influencing specimen attempt viability</i></p> | <p>Procedural Feasibility</p> <p><i>Encounter-level acquisition stability within defined workflow parameters</i></p> | <p>Trust Sustainability</p> <p><i>Signals of longitudinal engagement risk following specimen encounters</i></p> |
|--|---|--|

Each domain is observable without analytic instrumentation and without performance comparison.

Observational Architecture

Access Before Analysis™ utilizes structured descriptive observation within defined pediatric cohorts and institutional contexts. Documentation remains limited to:

- Access attempt patterns
- Encounter stability indicators
- Workflow friction signals
- Acquisition feasibility outcomes

No analyte data, hemolysis indices, or performance metrics are collected. No comparative claims are made.

Detailed cohort definition, variable mapping, and observation structure are developed collaboratively and are not included in this overview.

Deliverable

A structured synthesis framework characterizing:

- Patterns of access variability
- Encounter-level feasibility conditions
- Workflow constraints
- Implementation boundary considerations

This synthesis may inform future quality, implementation, or adoption discussions while remaining fully upstream of analytic or regulatory evaluation.

Guardrails

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| <p>Observational</p> | <p>Non-Comparative</p> |
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|------------------------------|------------------------------|
| Device-Agnostic | Regulatory-Aligned |
| Non-Analytic in Scope | No Performance Claims |

No superiority positioning.

Alignment

Access Before Analysis™ is an independent, trademarked methodology currently in structured pilot-stage development. Institutional or research alignment inquiries are welcomed.

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