

## Background and Rationale for Public Health Laboratory Replacement

The Department for Public Health (DPH) Division of Laboratory Services (DLS) is a **high-complexity clinical reference laboratory and select agent facility** (e.g., bioterrorism weapons and toxins) providing specialized and otherwise unavailable services required by state and federal statutes and regulations to ensure the health and safety of Kentuckians.

KDPH DLS currently occupies a **30+ year old physical plant** with numerous serious and unresolved deficiencies putting the laboratory at near-term risk for service disruptions, employee workplace injury, and loss of mandatory laboratory accreditation required to provide essential services.

Multiple issues imperil DPH DLS operations and generally fall within the following domains:

- **Outdated and failing infrastructure** (e.g., improper temperature and humidity regulation, inadequate and/or unsafe air exhaust, electrical and plumbing failures, etc.)
- **Obsolete, end-of-life mission critical equipment** (e.g., autoclaves, chillers, biosafety hoods, staff safety decontamination showers and eyewash stations, etc.)
- **Extensive deferred maintenance** including recurrent roof water leaks that jeopardize expensive, highly sensitive laboratory analyzers and other equipment
- **Insufficient square footage** to support necessary service and equipment expansion compounded by an outdated floorplan impeding operational efficiencies

Urgent action is needed to avert disruption to essential services provided by DPH DLS in fulfillment of statutory and regulatory mandates for which in-state alternatives often do not exist including:

- **Newborn screening** for all approximately 53,000 annual live births in KY; no in-state alternative
- **Federal Select Agent/Biosafety Level 3 analysis** (a.k.a. “white powder”); no in-state alternative
- **Animal necropsy lab** with rabies being the most well-known example
- **Subspecialty bacterial, viral, and fungal culture and genetic sequencing** sub-typing services supporting Kentucky hospitals and clinical laboratories
- A long list of **environmental and food safety testing services** for which the state is mandated by federal/state statute or regulation as the designated entity to perform analysis
- DLS also **validates in-state laboratories** when they acquire certain new capabilities

KDPH DLS is unlike any other laboratory facility operated in the Commonwealth of Kentucky. It provides unique, mission-critical services often unavailable anywhere else within the state. Were the laboratory to fail, contracted services provided by out-of-state facilities at substantial additional expense would become an immediate necessity. Urgent action is recommended.