METADATA last updated: 2026-03-18 RT file_name: _context-commentary_regulatory-surveillance.md category: regulatory subcategory: surveillance gfile_url: https://docs.google.com/document/d/1dFoISqFrvoEAitKyEkhKsZAPES7O-5IqHUTIGLqZ8S0 words: 1303 tokens: 1761

CONTENT

Context

Testing Types: Diagnostic, Screening, and Surveillance

During the COVID-19 pandemic, U.S. testing was categorized into three overlapping purposes:

- **Diagnostic testing**: Testing an individual when there is reason to suspect infection (symptoms or known exposure). Results are returned to the individual and their healthcare provider. The test must be FDA-authorized and is often processed in a CLIA-certified laboratory.
- **Screening testing**: Testing an individual without symptoms or known exposure, with the intent of making individual decisions based on results (e.g., return to school or work). Like diagnostic testing, screening requires FDA-authorized tests and results are returned to individuals.
- **Surveillance testing**: Population-level monitoring, often but not always using de-identified specimens. Results are not returned to individuals and are not to be used for individual decision-making. Surveillance testing does not require FDA authorization or CLIA certification.

Clarification: "Surveillance" in This Archive

Throughout this `regulatory/surveillance` subcategory and elsewhere in the FloodLAMP archive, "surveillance" refers to non-diagnostic, non-clinical testing programs designed to detect and limit the spread of COVID-19 in schools, workplaces, and communities. It does not refer to wastewater surveillance or genomic variant surveillance, both of which are distinct modalities covered in the AI-generated report referenced below. The absence of a clear regulatory category and standardized terminology for this type of frequent, pandemic stop-the-spread testing is itself a significant gap in pandemic preparedness and response frameworks. There is no good name for it and no established regulatory pathway — an unsolved problem that affected programs like FloodLAMP throughout the pandemic.

Key Documents in This Subcategory

For the authoritative regulatory definitions, two government documents provide the clearest framing:

- FDA Website - COVID-19 Test Uses_ FAQs on Testing for SARS-CoV-2 (updated 2023-09-29) — The FDA's post-crisis summary of diagnostic, screening, and surveillance definitions, including examples and CLIA/setting requirements.
- CDC - Testing Strategies for SARS-CoV-2 (includes Surveillance 12-28-2021) — Includes a summary matrix comparing the three testing strategies across settings, reporting requirements, and whether results may be returned to individuals.

FloodLAMP's own framing of how it operated under surveillance guidance is documented in:

- FloodLAMP Surveillance FAQ and Links (June 2022 DRAFT) — Contrasts diagnostic and surveillance testing, cites CMS/FDA guidance, and explains FloodLAMP's compliance posture. Includes FAQ-style responses prepared for the Coral Springs pilot program.
- FloodLAMP Surveillance Information (Aug 2021 INTERNAL) — A detailed internal memo on the regulatory framing for pooled non-diagnostic surveillance, including CMS enforcement discretion citations, an exchange between NIH Director Francis Collins and CMS Administrator Seema Verma on referral pathways, and the eCFR research-lab exemption.

Two outside analyses by professionals that were shared with us are also included:

- Memo - Surveillance Authority Plain-language Research (Jan 2021 from Senior Medical Director in Healthcare Industry) — A plain-language digest of FDA/CMS surveillance framing and the conditions under which presumptive positives may be routed to CLIA confirmatory testing.
- Memo - USA Surveillance Strategy (Sept 2021 from non-FloodLAMP Healthcare Attorney) — Guidance confirming that surveillance testing is generally not regulated when de-identified and no individual results are returned, and recommending coordination with local public health officials.

For a comprehensive treatment of the surveillance testing regulatory landscape during COVID-19 — including the Seattle Flu Study/SCAN case study, school-based surveillance controversies (SafeGuard/New Trier), and the post-PHE transition to wastewater and genomic surveillance — see the AI-generated report: _AI_Covid_Surveillance_Testing_Screening_Report.

Commentary

Navigating the Surveillance Framework

Surveillance testing was a regulatory gray area, and operating FloodLAMP's testing programs under this framework was a significant challenge. At the same time, the surveillance designation provided meaningful flexibility.

Communicating Results Without Giving "Results"

The central operational challenge was adhering to the requirement that surveillance programs not deliver "individual patient results." FloodLAMP's approach was to take the FDA's and CMS's language literally: when a sample indicated the presence of SARS-CoV-2, participants were told only that they were "referred to follow-up clinical testing." FloodLAMP did not tell participants they were positive or negative, and the company emphasized this distinction and terminology with program administrators.

This approach was informed by what happened at other programs. The CMS notice letter in this archive (December 2020) was sent to surveillance program operators instructing them to stop using the language "results of potential clinical significance." It was FloodLAMP's understanding, received secondhand, that this terminology had been adopted by operators attempting to comply while still communicating something to participants. In practice, everyone involved — operators, participants, and regulators — likely understood that phrasing to mean the surveillance test was positive. FloodLAMP chose to use the FDA's language, and a "referral to follow-up (clinical) testing" along with the explanation that we were not allowed to give "positive/negative" results to individual participants. The resulting communication was initially confusing for participants and program admins, but after a few repetitions, they understood. This kind of linguistic dance does not serve the public interest during a pandemic.

The Fundamental Regulatory Gap

The core problem was that the FDA did not distinguish between two very different kinds of "individual decisions." On one hand, there are clinical medical decisions: using a test result as a diagnosis and relying on it for treatment. On the other hand, there are public health mitigation decisions such as going home from school or work, isolating from family members, and getting a follow-up diagnostic test. In FloodLAMP's programs, the individual actions triggered by surveillance testing were of the second kind — participants went home, isolated, and in nearly all cases obtained confirmatory clinical testing (antigen, PCR, or both).

A better framework for pandemic screening would require that public health screening programs mandate follow-up confirmatory testing for flagged participants and that participants report those results back to the program. This would serve two purposes: providing the comparison data

needed to evaluate the screening program's performance, and codifying the principle that screening test results should not be the basis for medical decisions.

The Coral Springs Experience

The uncertain regulatory status of surveillance nearly prevented FloodLAMP's first major program from proceeding. The Coral Springs pilot covered municipal staff and first responders in a city of approximately 140,000 people and represented FloodLAMP's first significant commercial engagement. The city attorney raised concerns requiring due diligence on the surveillance framework. FloodLAMP was not fully informed of the internal discussions but provided supporting documentation, such as that in the `FloodLAMP Surveillance FAQ and Links (June 2022 DRAFT)` file. The matter reportedly came to a head in a meeting involving city officials, the medical director, regulators (from both FDA and CMS), and at least one elected representative (state or federal level, we do not know). The outcome was a "green light" for the program, though FloodLAMP never received any correspondence about that from CMS or the FDA. (For more on the Coral Springs pilot, see the `pilots/pilot-data` subcategory.)

Surveillance as a Fallback

Operating under the surveillance framework was not FloodLAMP's first choice — it was a fallback. The company had submitted its test to the FDA for Emergency Use Authorization as an open-source protocol in the model of SalivaDirect (see `regulatory/open-euas`), and had applied to the RADx program, but could not secure authorization, engagement, or even substantive attention through either channel. The opportunity to operate surveillance programs came about through our contact with EMS leadership and the FTFC conference in South Florida in mid 2021, where we offered pooled testing and made a presentation. One of the key executives at FloodLAMP had prior experience with surveillance and relationships with other operators of surveillance programs. That combined with the pull we were getting from the EMS community, who simply needed better, more effective testing/screening for their critical first responders, led us to do the FloodLAMP surveillance "pilot programs". These programs were very effective for the organizations that implemented them.

The primary commentary on FloodLAMP's regulatory experience, including EUA submissions and FDA correspondence, is in the `regulatory/open-euas` subcategory.