FDA Update: IVD Fentanyl Testing

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FDA regulated DoA tests

- In Vitro Diagnostic (IVD) drug of abuse (DoA) tests are intended to detect the presence of drugs in human specimens.
- These tests are class II devices with moderate risks and require 510(k) clearance prior to marketing.
  - Tests vary in complexity and rapidity.
Current IVD Landscape

- FDA has cleared IVD laboratory-based tests, point of care tests, and visually read test strip screening assays for drugs of abuse.

- These tests are available individually as well as part of drug panels (12+ analytes).

- All current FDA-cleared IVDs to detect fentanyl in human specimens are instrument-based tests.
FDA-cleared fentanyl IVDs

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
Current fentanyl IVD Landscape

- In December 2022, FDA cleared the first fentanyl test for use at the point-of-care (details on next slide)

- No visually read test strip for fentanyl has yet been cleared. This represents an unmet public health need.

  “substance use disorder treatment providers… must send samples to offsite CLIA-certified laboratories for fentanyl testing… this delay can lead to challenges in initiating the appropriate substance-specific treatment…”- Governor Charles Baker

- We look forward to working with IVD developers to bring IVD fentanyl test strips to the US market.
Fentanyl IVDs: developments
Thank you!