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Aspyre® Lung

Clinical Research Summary

Evaluation of the Aspyre® Lung targeted variant panel

A rapid, low-input solution for NSCLC biomarker testing and experience from three independent sites

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Background

While there is no shortage of approved targeted therapeutics to address driver mutations in NSCLC, many patients are not tested for these alterations due to gaps in biomarker testing access. Challenges in comprehensive molecular testing for biomarkers of NSCLC include:

- complexities associated with the need to assess the presence of multiple variants
- costs of running multiple sequential assays per sample
- high assay quality control (QC) failure rates
- need for rapid turnaround time
- insufficient tissue samples.

Aspyre Lung addresses gaps in multiplexed testing by simultaneously analyzing DNA and RNA, detecting 114 actionable genomic variants across 11 clinical practice guideline-recommended genes. This study was conducted to assess the ease of adoption and performance of Aspyre Lung in two third-party laboratories, testing 77 samples and comparing results across sites and with an orthogonal method.

Key Findings

- The Aspyre Lung assay was established at two academic centers and tested using 61 formalin-fixed paraffin-embedded (FFPE) and 16 cytology samples.
- The clinical samples were run unsupervised after three training runs (≤ 3 days), using standard laboratory equipment, including a thermocycler and real-time PCR instrument.
- The reproducibility across all samples was high (Table 1), and concordance with the orthogonal NGS-based method was high.
- **Aspyre Lung identified a *ROS1* fusion (confirmed by a tie-breaker method) that was missed by NGS.**

	Reproducibility (inter-run precision) between three sites %, (95% confidence intervals)	**Reproducibility AND concordance with NGS** %, (95% confidence intervals)
FFPE lung tissue samples	PPA: 100.0 (95.4-100.0) NPA: 99.99 (99.95-100.0)	PPA: 96.2 (89.2-99.2)* NPA: 99.97 (99.92-99.99)
Non-FFPE samples†	PPA: 100.0 (88.4-100.0) NPA: 99.93 (99.63-100.0)	PPA: 100.0 (88.4-100.0) NPA: 99.93 (99.63-100.0)

* This figure is a result of the *ROS1* fusion that was missed by NGS.

Table 1 - Summary comparison of variant profiling results between sites. PPA: positive percent agreement. NPA: negative percent agreement.

† Peritoneal fluid, pleural effusion, fine-needle aspirates (FNA), FNA rinses and fresh tissue

Participating Sites

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