The current 23- and 35-gene expression profile (GEP) ancillary diagnostic testing workflow for difficult cutaneous melanocytic lesions increases the rate of actionable results to 99%.

Results

Table 1. Performance Cohort accuracy metrics from the current GEP workflow

<table>
<thead>
<tr>
<th>Performance Cohort, n=350</th>
<th>GEP</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>96.0%</td>
<td>92.0% - 99.0%</td>
</tr>
<tr>
<td>Specificity</td>
<td>87.8%</td>
<td>80.8% - 93.8%</td>
</tr>
<tr>
<td>PPV</td>
<td>89.0%</td>
<td>83.8% - 94.1%</td>
</tr>
<tr>
<td>NPV</td>
<td>95.6%</td>
<td>91.1% - 98.9%</td>
</tr>
</tbody>
</table>

*Confidence interval; GEP, gene expression profile; NPV, negative predictive value; PPV, positive predictive value

Clinical test results were analyzed over a 6-month period. The 23-GEP test gave an actionable result of benign or malignant in 77.1% of cases (Table 2), which is comparable to past reporting in ambiguous cases for this test.

Nonactionable classifications of the 23-GEP test were 22.9% (13.3% intermediate and 9.6% technical failure). These cases then underwent testing with the 35-GEP and an additional 22.2% of originally submitted cases received an actionable result. Only 0.6% of cases received an intermediate result (i.e., from both tests); the technical failure rate was 0.1% (Table 2).

This GEP workflow increased the rate of an actionable report from 77.1% to 99.3% when compared with 23-GEP testing alone (Table 2). The GEP test results overall were 60.2% benign, 39.1% malignant, 0.6% intermediate, and 0.1% technical failure.

The median turnaround time for sample processing was 4 business days, (Table 2) and was only increased by 1 day when both GEP tests were run.

Table 2. Clinically actionable GEP test results

<table>
<thead>
<tr>
<th>Clinical Actionable</th>
<th>Nonactionable</th>
</tr>
</thead>
<tbody>
<tr>
<td>GEP</td>
<td>77.1%</td>
</tr>
<tr>
<td>Subsequent 35-GEP</td>
<td>22.2%</td>
</tr>
<tr>
<td>Overall Results</td>
<td>99.3%</td>
</tr>
</tbody>
</table>

*Actionable: sum of benign and malignant test results; ‡Nonactionable: sum of intermediate and technical failure test results when the date of receipt of tissue by the GEP gene expression profile

References


Conclusions

Though either GEP test can be run individually, the current GEP workflow collectively leverages the strengths of both independent GEP assays.

The GEP workflow demonstrated a high rate of accuracy in the Performance Cohort cases, with 96.0% sensitivity and 87.8% specificity.

The current GEP workflow for ambiguous melanocytic lesions has substantially improved reporting of clinically actionable results from a historic rate of ~77% for the 23-GEP alone to over 99%.

Acknowledgments & Disclosures

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