Laboratory Developed Tests: Guidelines
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Acknowledgments:

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada’s health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada’s federal, provincial, and territorial governments, with the exception of Quebec.
Research Question
1. What are the evidence-based guidelines regarding the use of laboratory developed tests?

Key Findings
No evidence-based guidelines were identified regarding use of laboratory developed tests.

Methods
A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. Methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses and guidelines. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 1997 and March 10, 2017. Internet links were provided, where available.

Selection Criteria
One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

<table>
<thead>
<tr>
<th>Population</th>
<th>Patients having samples analyzed by laboratory developed tests</th>
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<tbody>
<tr>
<td>Intervention</td>
<td>Laboratory developed tests in chemistry, toxicology, genetics, molecular biology, microbiology, pathology, or any other area</td>
</tr>
<tr>
<td>Comparator</td>
<td>No comparator</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Guidelines</td>
</tr>
<tr>
<td>Study Designs</td>
<td>Health technology assessments, systematic reviews, meta-analyses, evidence-based guidelines</td>
</tr>
</tbody>
</table>
Results

Rapid Response reports are organized so that the higher quality evidence is presented first. Normally, health technology assessment reports, systematic reviews, and meta-analyses are presented first; however, in reports where guidelines are primarily sought, the aforementioned evidence types are presented in the appendix.

No evidence-based guidelines were identified regarding use of laboratory developed tests.

References of potential interest are provided in the appendix.

Guidelines and Recommendations
No literature identified.
Appendix — Further Information

Health Technology Assessments


Systematic Reviews – Alternate Outcome


Clinical Practice Guidelines – Unclear Methodology


Review Articles


Additional References
