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**Technical Guidelines for preparing assessment reports for the Medical Services Advisory Committee -
Service Type: Investigative**

Dear Nicola

Thank you for the opportunity to respond to the consultation *Technical Guidelines for preparing assessment reports for the Medical Services Advisory Committee - Service Type: Investigative*. Please find below the IVD Australia response.

Yours sincerely



CEO
IVD Australia

We submit the comments below in two categories *Specific* and *Additional Concerns*.

IVD Australia Comments

Specific

Overall, the IVD Australia believes that the Guideline is well-suited to the task of providing detailed advice to assist applicants with determining content and presentation of submissions of evidence for consideration by MSAC and the Evaluation Sub-committee (ESC).

The Guideline appears to be consistent with best practice and we would like to acknowledge the efforts of MSAC in engaging with industry, particularly when reviewing policies and guidelines. The process of continuous review and improvement is appreciated.

Part 1, Section 3 states “Although the medical service budget is not ‘capped’ in Australia...”¹ which overlooks the long history of negotiation of the cap on per annum growth in industry-wide pathology funding outlays, which has an impact on the introduction of new technologies and services within Medicare.

Evidence for Point-of-Care tests is not covered in these Guidelines.

Additional Concerns

The application process is intimidating and this is seen by a low up-take by the IVD Industry. There is a lack of training and little guidance prior to the pre-application phase meetings. It would be beneficial to industry have a better understanding of the major failings/deficiencies in MSAC / HTA submissions and potential training opportunities

There also remains concern of the time-frame for application outcome (particularly for companion diagnostic applications).

¹ MSAC, *Technical Guidelines for preparing assessment reports for the Medical Services Advisory Committee – Service Type: Investigative* (Version 1.3), p. 8.