**REPOSTAS PARA OS REVISORES**

- Os autores agradecem os comentários do editor e dos revisores, que se revelaram muito úteis na revisão do manuscrito. Todas as sugestões foram aceites pelos autores.

**Notas do editor:**

- *com o objectivo de optimizar a legibilidade do seu artigo e assim incrementar potencialmente as citações do mesmo, recomendamos que os conteúdos redigidos em inglês sejam revistos por um "native speaker", tradutor qualificado ou empresa especializada em serviços de "language polishing";*

- Our work was proofread by Proof-reading-service.com (https://www.proof-reading-service.com/en/).

- o resumo e o abstract não deverão incluir abreviaturas.

- As abreviaturas foram retiradas do resumo/abstract.

**Revisor A:**

Considering the relevance, originality, structure, extension and presentation, as well as priority regarding publication, I think the manuscript should be published in AMP

- Muito agradecemos a opinião do revisor A.

**Revisor B:**

Dear authors

Apparently most of the requested changes were not taken into account in this review.

- We are very thankfully by all comments. Moreover, we have accepted all suggestions. Please see below our replies, which are highlighted in blue in the paper.

Major comments:

1. The paper apparently not included the MD-DIV, please justify.

Considering the regulation 2017/746 of the European Parliament and of the council of 5 April 2017 about in vitro diagnostic medical devices (preliminary point 10), *all tests that provide information on the predisposition to a medical condition or a disease, such as genetic tests, and tests that provide information to predict treatment response or reactions, such as companion diagnostics, are in vitro diagnostic medical devices*. One alert on an in vitro diagnostic medical device was identified in Portugal (INFARMED, I.P. website) during 2017: a CE marking was not affixed in reagents for in vitro diagnostic. German customs have learned these reagents, which were not marketed in Portugal. Due the free movement of goods in European Union, INFARMED, I.P. have recommended that these reagents should not be purchased or used since, there is no evidence of their safety, quality or performance. This issue was updated in the paper (section of introduction, results and discussion).

2. It is very important to discuss these results, with results from other EU- countries (with similar dimension of Portugal) and not EU- countries (only Australia is referred), to improve the discussion and to update the references.

Introduction and Discussion were updated on these issues. Data of EU- countries (with similar dimension of Portugal) were presented and discussed, namely data of Czechia, Austria, Belgium and Sweden. Additionally, the number of safety alerts about MDs published in the FDA and TGA (2017 publications) were comparatively discussed. As required, references were updated.

3. Please justify why “The MDs from the safety alerts were not checked against the Portuguese Code of the Medical Device (CMD) and its respective Portuguese Nomenclature for Medical Devices (NPDM)”.

This information was not made available in the safety alerts published by INFARMED, I.P. (public safety alert) (please see the highlighted text in study limitations).

Minor comments:

Abstract – Discussão, please rewritten the phrase, that it is not clear

the definition of “extenso” and “proporcionalmente ligeiramente

- The phrases were rewritten. Thanks.