

血型产品说明书要求，血型检测试剂IVDR临床试验

产品名称	血型产品说明书要求，血型检测试剂IVDR临床试验
公司名称	国瑞中安集团-实验室
价格	.00/个
规格参数	
公司地址	深圳市光明区凤凰街道塘家社区光明高新产业园2号楼1层
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产品详情

说明书承载了产品预期用途、试验原理、试验方法、检测结果解释以及注意事项等重要信息，是指导实验室工作人员正确操作、临床医生针对检验结果给出合理医学解释的重要依据，因此，产品说明书是体外诊断试剂注册申报zui重要的文件之一。产品说明书的格式应符合《体外诊断试剂说明书编写指导原则》（国家食品药品监督管理总局通告2014年第17号）的要求，境外产品的中文说明书除格式要求外，其内容应尽量保持与原文说明书的一致性，翻译力求准确且符合中文表达习惯。产品说明书的所有内容均应与申请人提交的注册申报资料中的相关研究结果保持一致，如某些内容引用自参考文献，则应以规范格式对此内容进行标注，并单独列明参考文献的相关信息。

The instructions contain important information such as the intended use of the product, test principles, test methods, interpretation of test results, and precautions, and are an important basis for guiding laboratory staff to operate correctly and for clinicians to give reasonable medical interpretation of test results. Therefore, the product instructions are one of the most important documents for the registration and application of in vitro diagnostic reagents. The format of the product instructions shall comply with the requirements of the Guiding Principles for the Preparation of In Vitro Diagnostic Reagent Instructions (Circular No. 17, 2014 of the State Food and Drug Administration). In addition to the format requirements, the contents of the Chinese instructions for overseas products shall be consistent with the original instructions as far as possible, and the translation shall be accurate and conform to the Chinese expression habits. All contents of the product manual shall be consistent with the relevant research results in the registration application materials submitted by the applicant. If some contents are quoted from references, the contents shall be marked in a standardized format and the relevant information of the references shall be listed separately.