

To our clients about COVID-19 IgM/IgG antibody testing

Per our experience, false positive IgM can happen but can be largely eliminated if the procedure is done properly. FDA has emphasized that all quick lateral flow testing cannot be used as sole diagnosis of COVID-19. FDA recommends a confirmation with PCR. Therefore, at MVL, each IgM positive result, especially those with IgG negative results, must be repeated and confirmed by a different lateral flow kit.

Most FDA approved products have 2-3% false positive IgM because FDA asked for high sensitivity in their template for EUA. All false positive we have seen are IgM single positive without IgG positive. In real positive samples, 2-3% samples will be IgM single positive without IgG positive. If we assume 2% positive rate, the real IgM single positive would be around 0.05%. With 2.5% false IgM single positive rate, we could conclude that only 1/50 IgM positive is real. If we do see a single IgM positive, 98% chance we are seeing a false positive signal, although the specificity of the test is as high as 97.5%. To put this in real numbers, if we have 10,000 people tested, 250 will have IgM single positive, and 5 of the 250 may be truly positive.

有关 COVID-19 IgM / IgG 抗体测试

根据我们的经验，可能会发生IgM假阳性，但如果程序正确完成，则可以降低假阳性的发生率。FDA强调不能将抗体测试作为COVID-19的唯一检测诊断，并建议通过PCR进行结果确认。因此，在MVL检测的每个IgM阳性结果，特别是IgG阴性结果，必须重复并通过不同的 COVID-19 IgM / IgG 试剂盒进行确认。

**大多数FDA批准的产品都有2-3%的假阳性IgM，因为FDA要求产品高灵敏度。我们看到的所
有假阳性均为IgM单阳性，无IgG阳性。在真正的阳性样品中，有2-3%的样品是IgM单阳
性，而IgG没有阳性。如果我们假设阳性率为2%，则实际IgM单阳性将约为0.05%。假阳性
IgM阳性率为2.5%，我们可以得出结论，只有1/50 IgM阳性是真实的。如果我们确实看到单
个IgM阳性，则98%的可能性就是假阳性信号，尽管测试的特异性高达97.5%。因此，如果
测试了10,000人，250名IgM单阳性，则其中有5名测试者可能是真正的阳性。**