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Notice about MVL COVID-19 IgM/IgG antibody lateral flow testing

Dear Clients,

While false-positive IgM results can happen, they can be largely eliminated if the appropriate protocols are followed. FDA has emphasized that quick lateral flow testing cannot be used as the sole methodology for diagnosing COVID-19. The Agency recommends the use of PCR testing to confirm lateral flow testing results.

At MVL, each IgM positive result, especially those with IgG negative results, must be repeated and confirmed by a different lateral flow kit. As of December 12, 2020, we have tested 126 PCR negative cases by IgM/IgG antibody testing. Up until now, we have not seen a single positive case, which indicates that specificity of our IgM/IgG antibody testing is 100%.

### **有关 COVID-19 IgM / IgG 抗体测试**

**IgM假阳性可能会发生，但如果程序正确完成，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。**

**截至2020年12月12日，我们已通过IgM / IgG抗体检测方法检测了126例PCR阴性顾客。我们还没有看到一个阳性的案例。该结果表明，到目前为止，我们的IgM / IgG抗体测试的特异性为100%。**