

Hi Drs. Bien-Willner and Brito,

We are formally requesting MolDX to consider our request for an LCD on the PrismRA® test by Scipher Medicine.

We have included all the required materials and provided a draft LCD for your consideration (in the attached zip file).

Please see below for a table of contents:

1. Executive summary
2. Technical assessment summary form (M00116)
3. ACCE 44 answers
4. Complete AV and CV documents
 1. PrismRA validation report
 2. Supporting AV documents
 1. CCP verification report
 2. CRP verification report
 3. PAXgene blood kit handbook
 4. PMID 12406972
 5. Scipher PrismRA validation concordance report
 6. Scipher PrismRA validation report
 3. Published PrismRA CV paper
5. Proficiency testing results (from the last cycle)
 1. First half of SM PT 2020
 2. Second half of SM PT 2020
6. PrismRA draft LCD
7. Appendix
 1. Results
 1. Failed result
 2. High result
 3. Moderate result
 4. No signal result
 5. Test report interpretation guide
 6. Very high result
 2. Sample collection instructions
 3. Technical specifications sheet
 4. Test requisition form
8. Other Scipher Medicine publications
 1. Accepted decision impact paper
 2. Published clinical utility paper
9. Links to external pertinent publications
 1. 2015 ACR guidelines
 0. <https://onlinelibrary.wiley.com/doi/epdf/10.1002/art.39480>
 2. 2019 EULAR guidelines
 0. <https://ard.bmj.com/content/annrheumdis/79/6/685.full.pdf>

Please contact me with any questions. If any of the files do not open, please let me know so I can re-send, thank you for your time.



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Certified Genetic Counselor

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