Chair and members of the Administrative Rules Committee, thank you for the opportunity to present testimony on behalf of the North Dakota Board of Clinical Laboratory Practice. On September 9, 2025, the Board adopted amendments to Administrative Code Chapters 96-02-03 and 96-02-10, which have since been reviewed and approved by the Attorney General's office as to their legality. These changes are now submitted for publication in the North Dakota Administrative Code.

The first set of amendments concerns fees under Chapter 96-02-03. The Board has adjusted initial licensure fees, renewal fees, late fees, and provisional permit fees, increasing each category by approximately forty dollars. These adjustments are prorated depending on the date of application and are designed to ensure that licensure fees adequately cover the operational costs of the Board. According to the fiscal note, the Board currently operates at a negative balance, and the new fee structure is expected to generate approximately $109,000 in additional biennial revenue, stabilizing finances without reliance on the general fund.

The second set of amendments addresses exemptions from licensure under Chapter 96-02-10. The Board has updated and clarified the list of FDA-waived tests and methods that may be performed under supervision without requiring licensure. These include rapid immunoassays for conditions such as influenza, strep A, hepatitis C, respiratory syncytial virus, and SARS-CoV-2, as well as specific instruments like the Alere Cholestech analyzer, the Abaxis Piccolo Xpress, and the i-STAT creatinine test. In addition, the amendments strengthen supervision requirements by mandating annual competency assessments, documentation of training retained for three years, monthly cleanliness testing for DNA and RNA detection systems, and prompt reporting of supervised personnel to the Board. Failure to meet these supervision standards is explicitly defined as unprofessional conduct subject to disciplinary action.

Public input was received in writing from two parties the board reviewed the comments and decided to proceed with the current rules. The Board declined to add the requested tests at this time, noting that further discussion is warranted. No oral comments were received during the public hearing.

In closing, these amendments modernize the Board's fee structure to ensure financial sustainability, clarify exemptions for waived testing methods, and strengthen supervision standards to protect public health. The Board has considered public input carefully and remains open to future exemption requests. We respectfully submit these rules for your review and approval.