Dear MolDx team,

Please see attached request for coverage of the DecisionDx-SCC (ZBBLD).

As we discussed during our recent conference call, the DecisionDx-SCC test is intended to be used by healthcare providers in the immediate post-diagnostic period to adjust treatment plans for patients with high-risk cutaneous squamous cell carcinoma (SCC). The clinical validity and utility of the test have been demonstrated in 4 peer-reviewed articles. The DecisionDx Melanoma test is only performed in Castle Biosciences CLIA registered clinical laboratory which is CAP and NYSDOH accredited.

Please see all documents attached in a ZIP file. In addition to a document outlining the rationale for this coverage request and a draft LCD (based on your recent draft LCD for Prognostic and Predictive Molecular Classifiers for Bladder Cancer (DL38576), we have included the following documents per the MolDX Technical Assessment Submission Checklist and Questionnaire (M00151, V5):

1. Technical Assessment Form (M00116 v2) for DecisionDx-SCC (ZBBLD)
2. Coverage Request for DecisionDx-SCC (ZBBLD)
3. Executive Summary for DecisionDx-SCC (ZBBLD)
4. DecisionDx-SCC (ZBBLD) Draft LCD
5. Laboratory Validation report for DecisionDx-SCC (ZBBLD) (includes section on proficiency testing)
6. DecisionDx-SCC (ZBBLD) Test Requisition Form (TRF)
7. DecisionDx-SCC (ZBBLD) Sample Reports
   a. Class 1
   b. Class 2A
   c. Class 2B (includes example requisition)
8. Most recent inspection results from CAP and NYSDoH
9. Proficiency Testing SOPs from Castle Biosciences laboratory
   a. Proficiency Testing Procedure
   b. Levy-Jennings analysis Procedure

10. Powerpoint presentation from May 13th meeting
11. MolDX Technical Assessment Submission Checklist and Questionnaire (M00151, V5)
12. Publications
    a. Clinical Validation – Wysong et al. J Am Acad Dermatol 2020
    b. Clinical Utility
        i. Teplitz et al. J Drugs Dermatol 2019
        ii. Farberg et al. Curr Med Res Opin 2020
        iii. Litchman et al. Curr Med Res Opin 2020

Please confirm receipt of this request and ability to open the attached documents. Also, please let us know if you have any question.

Sincerely,

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