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| **IMPORTANT:** If you are the Laboratory Director for a laboratory that performs any testing in the subspecialty of Cytology, please read the form carefully, sign and return to COLA. | **COLA ID** | |
| | **Laboratory Name** | |
| | **Physical Address** | |

This laboratory shall comply with the requirements for accreditation established by COLA. It shall permit COLA personnel to review laboratory records, proficiency testing program evaluations, and other relevant information. I authorize COLA to perform on-site inspections and to review Cytology slides and reports, whether routine or revisit. I further authorize COLA to evaluate complaints against the laboratory.

As a condition of using COLA accreditation to meet the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), I make the following representations:

a. Workload limits will be established by the Technical Supervisor for each testing person who performs primary cytology screening, according to COLA Cytology requirements found in the COLA Laboratory Accreditation Manual. Workload limits for each testing person will be re-evaluated at least every six months.
b. The laboratory will participate in a CMS-approved proficiency testing program for gynecologic cytology.
c. Each testing person who examines gynecological Cytology preparations will be enrolled in a CMS-approved Cytology proficiency testing program annually. Records will be made available to COLA during survey and upon request between surveys.
d. Discrepancies identified via retrospective reviews, rescreening of 10% negative pap tests, Cytology/Histology comparisons, proficiency testing results, review of laboratory and individual Cytology statistics or any other quality assessment activity will be investigated, documented, and a corrective action plan defined and implemented.
e. I recognize the unique requirements for Cytology under the CLIA regulations, and I agree to comply with all requirements.
f. I understand that COLA has an obligation to utilize diagnostic rescreening of Cytology cases, in response to identification of significant noncompliance as result of an on-site survey or complaint investigation. I recognize that this is a necessity in the interest of patient care, and agree to cooperate fully should a diagnostic rescreening event be required.
    a. I agree to allow COLA and its representatives to rescreen Cytology slides at my facility, and will provide the necessary space and one or more microscopes for use during the diagnostic re-screening survey.
    b. I understand that my laboratory will be responsible for the expenses associated with the diagnostic rescreening, which includes travel for the survey team and contracted fees for independent cytotechnologists.

By typing my name below, I hereby agree to hold COLA, its members, surveyors, officers, directors, employees and agents harmless from any complaint, claim, or damage arising out of any action or omission by any of them in connection with this enrollment process, any inspection of the laboratory, or any decision to accredit or not accredit the laboratory. I understand that the decision as to whether this laboratory qualifies for accreditation by COLA rests solely and exclusively in COLA and that the decision of COLA is final. I have read and understood this statement and intend to be legally bound by it.

| **Laboratory Director** | **Date** |
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