

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0505003	(X3) Date Survey Completed 01/16/2019
Name of Provider or Supplier Clinical Pathology Labs Inc	Street Address, City, State 9200 Wall Street Attn Karen Pruett, Austin, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5032	<p>CYTOLOGY CFR(s): 493.1221</p> <p>If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, record review and interviews it was determined that the laboratory failed to follow written policies and procedures to document the rescreening results of retrospective reviews (refer to D5627) and failed to maintain a record of the date that cases were reviewed (refer to D5787). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology. Based on review of laboratory policies and procedures, record review and interviews it was determined that the laboratory failed to follow written policies and procedures to document the rescreening results of retrospective reviews (refer to D5627); and failed to maintain a record of the date that cases were reviewed (refer to D5787). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology.</p>
D5627	<p>CYTOLOGY CFR(s): 493.1274(c)(4)</p> <p>Records of initial examinations and all rescreening results must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and</p>

interviews it was determined that the laboratory failed to follow written policies and procedures to document the rescreening results for 61 of 65 retrospective reviews from November 2018. Findings include: 1. The laboratory failed to follow the procedure AUS250575SOP titled QUALITY MANAGEMENT PROGRAM PROCEDURE which stated: "QUALITY ASSURANCE REVIEW: The results of rescreening previously reported cases, both normal and abnormal, are documented and shared with the responsible cytotechnologist and pathologist." 2. The Survey Team reviewed records titled RANDOM PATH REVIEW for November 2018. The records documented the Cytotechnologist's rescreening results. a. Cytotechnologist H failed to document the rescreening results for 42 of 43 cases. Cases include: - ZM048621 - ZM063163 - ZM886420 - ZM887310 - ZM938099 - ZM939229 - ZM946063 - ZM946733 - ZM948390 - ZM950271 - ZM951368 - ZM962782 - ZM964473 - ZM970149 - ZM970748 - ZM973445 - ZM985615 - ZM988027 - ZM992791 - ZN006631 - ZN011981 - ZN013706 - ZM926131 - ZM934877 - ZM937556 - ZM938947 - ZM942153 - ZM943885 - ZM952552 - ZM953433 - ZM954781 - ZM969291 - ZM971119 - ZM972617 - ZM974246 - ZM974863 - ZM975047 - ZM976518 - ZM977954 - ZM982408 - ZM988288 - ZN014221 b. Cytotechnologist I failed to document the rescreening results for 19 of 22 cases. Cases include: - ZM886804 - ZM920961 - ZM928735 - ZM935328 - ZM943301 - ZM947571 - ZM949781 - ZM949790 - ZM949950 - ZM962693 - ZM962808 - ZM967368 - ZM968857 - ZM968964 - ZM974326 - ZM978236 - ZM989795 - ZM994454 - ZN026517 3. During an interview on January 14, 2019 at 3:00 PM, the Laboratory Manager and Cytology Supervisor confirmed these findings. 4. During an interview on January 15, 2019 at 10:25 AM, Technical Supervisor B confirmed these findings.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interviews it was determined that the laboratory failed to maintain a record of the date that 281 of 281 cases were reviewed in November 2018. Findings include: 1. The Survey Team reviewed records titled RANDOM WEEKLY PATH REVIEW from November 2018. The records documented the Cytotechnologist review diagnosis, reviewer's identity and date of the review. a. The Cytology Supervisor failed to document the date the review was performed for 205 of 205 cases. Cases include: - ZM675990 - ZM723184 - ZM727881 - ZM733411 - ZM734482 - ZM735532 - ZM736496 - ZM736816 - ZM737386 - ZM743759 - ZM753924 - ZM769058 - ZM771922 - ZM782819 - ZM787065 - ZM790857 - ZM808405 - ZM809028 - ZM813236 - ZM818662 - ZM820876 - ZM826001 - ZM840162 - ZM844072 - ZM848527 - ZM060260 - ZM885290 - ZM920862 - ZM930045 - ZM932504 - ZM939292 - ZM940570 - ZM942841 - ZM944111 - ZM944855 - ZM948531 - ZM950674 - ZM951475 - ZM952866 - ZM961201 - ZM961300 - ZM961631 - ZM963206 - ZM963912 - ZM968427 - ZM979224 - ZM984430 - ZM997536 - ZM877940 - ZM881451 - ZM912001 - ZM803042 - ZM824301 - ZM827269 - ZM873280 - ZM884695 -

ZM960569 - ZM910571 - ZM811751 - ZM856181 - ZM863416 - ZM873744 - ZM878802 - ZM879471 - ZM885182 - ZM894548 - ZM905660 - ZM920595 - ZM933833 - ZM042682 - ZM042898 - ZM749467 - ZM811868 - ZM815722 - ZM824178 - ZM824964 - ZM841876 - ZM853198 - ZM856485 - ZM856654 - ZM862007 - ZM869993 - ZM883043 - ZM890638 - ZM907735 - ZM916663 - ZM919235 - ZM874429 - ZM887991 - ZM890370 - ZM925368 - ZM047141 - ZM048695 - ZM883974 - ZM886671 - ZM935337 - ZM938203 - ZM939050 - ZM939185 - ZM939631 - ZM942019 - ZM942823 - ZM944102 - ZM948783 - ZM949261 - ZM952178 - ZM952768 - ZM958903 - ZM961758 - ZM968759 - ZM982023 - ZM990698 - ZN000459 - ZN005787 - ZM053917 - ZM960652 - ZN008180 - ZN008395 - ZN014731 - ZN016010 - ZN020489 - ZN024343 - ZN030171 - ZN033487 - ZN034733 - ZN035848 - ZN039801 - ZN041658 - ZN043920 - ZN044856 - ZN046716 - ZN048793 - ZN056900 - ZN076260 - ZN076359 - ZN078854 - ZN084181 - ZN084904 - ZN103939 - ZM049914 - ZN001311 - ZN016477 - ZN020676 - ZN023490 - ZN024657 - ZN025879 - ZN033450 - ZN034653 - ZN038401 - ZN039604 - ZN039874 - ZN040230 - ZN042271 - ZN044650 - ZN046313 - ZN048711 - ZN071021 - ZN087236 - ZN094151 - ZN107670 - ZN111171 - ZN111233 - ZN115312 - ZN008359 - ZN008591 - ZN023159 - ZN027372 - ZN027425 - ZN033601 - ZN035801 - ZN040249 - ZN040820 - ZN041237 - ZN043204 - ZN043901 - ZN045291 - ZN058495 - ZN058600 - ZN068689 - ZN071737 - ZN072396 - ZN078219 - ZN091856 - ZN091874 - ZN100900 - ZN104391 - ZN115143 - ZN061534 - ZN282212 - ZN310569 - ZN319260 - ZN340906 - ZN283846 - ZN324813 - ZM064330 - ZN287961 - ZN139092 - ZN198979 - ZN283784 - ZN307474 - ZN322846 - ZN332806 - ZN335156 - ZN346221 - ZN349222 b. Cytotechnologist J failed to document the date the review was performed for 76 of 76 cases. Cases include: - ZH473626 - ZM052160 - ZM055288 - ZM220800 - ZN061051 - ZN094581 - ZN100276 - ZN123548 - ZN127126 - ZN129784 - ZN134873 - ZN135066 - ZN136681 - ZN149400 - ZN151471 - ZN159971 - ZN161066 - ZN163098 - ZN164415 - ZN165593 - ZN168890 - ZN169467 - ZN169986 - ZN178930 - ZN185550 - ZM052910 - ZM055171 - ZM069926 - ZM220775 - ZN061015 - ZN090957 - ZN092361 - ZN099649 - ZN122792 - ZN126675 - ZN134050 - ZN140066 - ZN148411 - ZN152441 - ZN153019 - ZN154811 - ZN156880 - ZN157751 - ZN160050 - ZN165655 - ZN166429 - ZN166939 - ZN168951 - ZN185934 - ZN187081 - ZM054899 - ZN060439 - ZN077801 - ZN084351 - ZN091711 - ZN099602 - ZN103213 - ZN120949 - ZN121150 - ZN121991 - ZN122578 - ZN130570 - ZN132396 - ZN137329 - ZN138854 - ZN142445 - ZN146168 - ZN163113 - ZN171142 - ZN178813 - ZN184463 - ZN192699 - ZN193140 - ZN193284 - ZN195977 - ZN044785 2. During an interview on January 14, 2019 at 3:00 PM, the Laboratory Manager and Cytology Supervisor confirmed these findings. 4. During an interview on January 15, 2019 at 10:25 AM, Technical Supervisor B confirmed these findings.