Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1062976	10/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dell Childrens Medical Center Of Central Texas	4900 Mueller Blvd, 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	CYTOLOGY CFR(s): 493.1221 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. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, record review, observation and interviews it was determined that Facility A (CLIA #45D1062976) failed to ensure records were maintained of the number of slides prepared for cytology cases (refer to D5203); failed to establish written policies and procedures to assess competency of two of two Cytotechnologists performing cytology processing (refer to D5209); failed to establish written policies and procedures for eight laboratory processes (refer to D5403); failed to follow written policies and procedures for the evaluation and comparison of six of six laboratory statistics, and failed to document six of six required annual statistics for 2016 and 2017 (refer to D5629); failed to establish written policies and procedures for establishing workload limits, reassessing workload limits, prorating workload limits and maintaining workload slides and hours (refer to D5633, D5635, D5637, D5641, D5645); failed to establish written policies and procedures to ensure that corrected reports indicated the basis for the correction on the report (refer to D5659); and failed to ensure that final test reports indicated the name and address of the laboratory location where the test was performed (refer to D5805). 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.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232

	The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, glass slide preparations and interviews it was determined that Facility A failed to establish written policies and procedures to ensure records were maintained to document the number of slides prepared for 63 of 63 cases from 2018. Findings include: 1. The Survey Team requested and Facility A failed to provide written policies and procedures to describe how Facility A documented the number of slides prepared for each case. 2. The Survey team reviewed 63 final test reports and the corresponding glass slides. Facility A failed to provide a record of the number of specimen slides prepared for 63 of 63 cases. Cases include: - DC18-57 - DC18-154 - DC18-277 - DC18-279 - DC18-313 - DC18-317 - DC18-344 - DC18-345 - DC18-346 - DC18-347 - DC18-348 - DC18-349 - DC18-350 - DC18-351 - DC18-352 - DC18-353 - DC18-354 - DC18-355 - DC18-356 - DC18-357 - DC18-358 - DC18-359 - DC18-360 - DC18-361 - DC18-362 - DC18-363 - DC18-364 - DC18-365 - DC18-366 - DC18-367 - DC18-368 - DC18-369 - DC18-370 - DC18-371 - DC18-379 - DC18-386 - DC18-387 - DC18-388 - DC18-389 - DC18-390 - DC18-391 - DC18-392 - DC18-393 - DC18-394 - DC18-395 - DC18-396 - DC18-397 - DC18-398 - DC18-400 - DC18-401 - DC18-402 - DC18-403 - DC18-404 - DC18-405 - DC18-406 - DC18-407 - DC18-408 - DC18-409 - DC18-410 - DC18-411 - DC18-412 - DC18-413 - DC18-566 3. During an interview on October 16, 2018 at 3:20 PM, the Anatomic Pathology Manager stated that the number of glass slides was supposed to be documented on the final test reports in the gross description of the specimen. 4. During an interview on October 17, 2018 at 1:00 PM, the Laboratory Director/Technical Supervisor A confirmed that Facility A failed to document the number of slides prepared for each specimen.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory polices and procedures and interview it was determined that Facility A failed to establish written policies and procedures to assess the competency of two of two Cytotechnologists performing cytology processing. Findings include: 1. The Survey Team requested and Facility A failed to provide written policies and procedures to describe Facility A's process for assessing the competency of the two Cytotechnologists performing cytology processing. Cytotechnologists include: - Cytotechnologist A - Cytotechnologist B 2. During an interview on October 16, 2018 at 2:05 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, glass slide preparations and interviews it was determined that Facility A failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. Cross refer to D5203, D5209 Findings include: 1. The Survey Team requested and Facility A failed to provide written policies and procedures for an ongoing mechanism to monitor and assess the quality of the general laboratory system. 2. During an interview on October 17, 2018 at 10:45 AM, the Survey Team asked the Laboratory Director/Technical Supervisor A if there was a mechanism to monitor the general laboratory system of Facility A. The Laboratory Director/Technical Supervisor A stated that Facility A performed a quality assessment review of cases but only looked at "diagnostics, demographics, and billing." a. Facility A failed to establish an ongoing mechanism to ensure records were kept to document the number of slides prepared for each specimen and to establish written policies and procedures to assess the competency of personnel performing cytology processing.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of 81 laboratory policies and procedures, laboratory records and interviews it was determined that Facility A failed to have written procedures for eight laboratory processes. Findings include: 1. The Survey Team requested and Facility A failed to provide written policies and procedures to describe Facility A's slide storage and retention requirements. a. During an interview on October 15, 2018 at 10:15 AM, Cytotechnologist A from Facility A stated that some slides were stored at Facility B

	(CLIA #45D0504523), Facility C (CLIA #45D0505053), and Facility D (CLIA #45D1076416). b. During an interview on October 15, 2018 at 12:10 PM, the Laboratory Director/Technical Supervisor A confirmed that slides were stored at Facility B, Facility C, and Facility D. The Laboratory Director/Technical Supervisor A further stated that slides were also stored at Facility E (CLIA #45D0505003). 2. The Survey Team requested and Facility A failed to provide written policies and procedures to describe how the Cytotechnologists and Technical Supervisors reported results into the laboratory information system (LIS). 3. The Survey Team requested and Facility A failed to provide written policies and procedures to describe the transport of specimens and slides between Facility A, Facility B, Facility C, and Facility D. 4. The Survey Team requested and Facility A failed to provide written policies and procedures to describe how nongynecologic specimens were processed. 5. The Survey Team requested and Facility A failed to provide written policies and procedures to describe how cell blocks were prepared. 6 The Survey Team requested and Facility A failed to provide written policies and procedures to describe nongynecologic staining using the Leica Autostainer XL. 7. The Survey Team requested and Facility A failed to provide written policies and procedures to describe how specimen slides were coverslipped using the automatic coverslipper. 8. The Survey Team requested and Facility A failed to provide written policies and procedures to describe how specimen slides were coverslipped manually. 9. During interviews on October 16, 2018 at 2:05 PM and October 17, 2018 at 1:00 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that Facility A failed to follow written policies and procedures for the evaluation and comparison of 6 of 6 laboratory statistics, and failed to document 6 of 6 required annual statistics for 2016 and 2017. Findings include: 1. The Survey Team reviewed the procedure titled CYTOLOGY STATISTICAL REPORTS which stated: "Dell Children's Medical Center cytology department will prepare an annual statistical summary report." "Monthly reports are printed and collected as part of annual statistics." "Annually record the sum of all monthly totals for each statistic." 2. The Survey Team requested and Facility A failed to provide Facility A's six required annual statistics. 3. During an interview on October 16, 2018 at 10:17 AM, Cytotechnologist A stated that Facility A compiled statistics that included cases reported at Facility B, Facility C and Facility D. Cytotechnologist A

	further stated that Facility E was responsible for the statistics on cases that Facility E sent to Facility A for review and reporting. 4. During an interview on October 16, 2018 at 2:05 PM, the Laboratory Director/Technical Supervisor A confirmed there were no annual statistics for cases reported at Facility A.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that Facility A failed to establish written policies and procedures to ensure that a maximum workload limit was established by Technical Supervisor A for three of three Technical Supervisors in 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and Facility A failed to provide written policies and procedures to ensure that workload limits were established by Technical Supervisor A for three of three Technical Supervisors who performed the primary evaluation of nongynecologic cytology specimens. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B - Technical Supervisor C 2. The Survey Team requested and Facility A failed to provide documentation that Technical Supervisor A established a maximum workload limit for the three Technical Supervisors in 2016, 2017 and to the date of the survey in 2018 3. During an interview on October 15, 2018 at 1:20 PM, the Laboratory Director /Technical Supervisor A confirmed there were no maximum workload limits established for the three Technical Supervisors.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that Facility A failed to establish written policies and procedures to ensure that the workload limit for three of three Technical Supervisors was reassessed at least every six months and adjusted when necessary in 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and Facility A failed to provide written policies and procedures to ensure that workload limits for three of three Technical Supervisors were reassessed at least every six months and adjusted when necessary in 2016, 2017 and to the date of the survey in 2018. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B - Technical Supervisor C 2. The Survey Team requested and Facility A failed to provide documentation that the workload limits for the three Technical Supervisors had been reassessed every six months for 2016, 2017 and to the date of the survey in 2018. 3. During an interview on October 15, 2018 at 1:20 PM, the Laboratory Director /Technical Supervisor A confirmed that workload limits had not been reassessed.

D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined; This STANDARD is not met as evidenced by: Based on review of laboratory polices and procedures, laboratory records and interview it was determined that the Facility A failed to establish written policies and procedures to ensure that the workload limit for three of three Technical Supervisors, when examining slides in less than an 8-hour workday and with duties other than slide examination, would be prorated using a period of eight hours to determine the number of slides that may be examined. Findings include: 1. The Survey Team requested and Facility A failed to provide written policies or procedures to determine how to prorate the workload limit for the three Technical Supervisors when time was spent on activities other than performing primary examinations of cytology slides. 2. The Survey Team requested and Facility A failed to provide documentation of prorated workload limits for the three Technical Supervisors in 2016, 2017 and to the date of the survey in 2018. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B - Technical Supervisor C 3. During an interview on October 15, 2018 at 1:20 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that Facility A failed to establish policies and procedures to ensure that Facility A maintained records of the total number of slides examined and the number of hours spent examining slides in each 24-hour period for three of three Technical Supervisors in 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and Facility A failed to provide written policies and procedures to ensure that Facility A maintained workload records to document the number of slides and time spent examining slides for three of three Technical Supervisors. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B - Technical Supervisor C 2. The Survey Team requested and Facility A failed to provide workload records to document the number of slides and time spent examining slides for the three Technical Supervisors who performed the primary examination of nongynecologic slides in 2016, 2017 and to the date of the

	survey in 2018. 3. During an interview on October 15, 2018 at 1:20 PM, the Laboratory Director/Technical Supervisor A confirmed that there were no workload records for the three Technical Supervisors.
D5659	CYTOLOGY CFR(s): 493.1274(e)(6) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the basis for correction. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that Facility A failed to establish written policies and procedures to ensure that corrected reports indicated the basis for the correction on the report. One of one corrected reports from June 2017 through the date of the survey in 2018 did not indicate the basis for the correction. Findings include: 1. The Survey Team requested and Facility A failed to provide written policies and procedures to describe Facility A's process to ensure that corrected reports indicated the basis for the correction. 2. The Survey Team reviewed one corrected report. The report did not include the basis for the correction. Report includes: DC17-292 3. During an interview on October 16, 2018 at 2:05 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews it was determined that Facility A failed to ensure that 20 of 20 final test reports from February through October 2018 indicated the name and address of the laboratory location where the test was performed. Findings include: 1. The Survey Team reviewed 20 random final test reports. Twenty of 20 final test reports did not indicate the name and address of the Facility A. Reports include: - XC18-6 - XC18-26 - MC18-5 - MC18-7 - MC18-11 - MC18-13 - MC18-25 - MC18-33 - UC18-363 - UC18-382 - UC18-402 - UC18-412 - UC18-423 - UC18-425 - UC18-427 - UC18-428 - UC18-431 - UC18-434 - UC18-436 - UC18-437 2. During an interview on October 16, 2018 at 11:40 AM, Cytotechnologist A confirmed the final test reports did not indicate the name and address of the laboratory location where the test was performed. 3. During an interview on October 16, 2018 at 2:05 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.

D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that Facility A failed to establish written policies and procedures for an ongoing mechanism to ensure final test reports indicated the name and address of the laboratory location where the test was performed. Cross refer to D5805 Findings include: 1. The Survey Team requested and Facility A failed to provide written policies and procedures for an ongoing mechanism to ensure final test reports indicated the name and address of the laboratory location where the test was performed. 2. During an interview on October 17, 2018 at 10:45 AM, the Survey Team asked the Laboratory Director/Technical Supervisor A if there was a mechanism to monitor the postanalytic system of Facility A. The Laboratory Director /Technical Supervisor A stated that Facility A performed a quality assessment review of cases but only looked at "diagnostics, demographics, and billing." a. Facility A failed to establish an ongoing mechanism to identify final test reports that did not indicate the name and address of the laboratory location where the test was performed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the review of laboratory policies and procedures, record review, observation and interviews it was determined that Facility A failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to fulfill the responsibility for the overall operation of Facility A and failed to ensure compliance with applicable regulations (refer to D6079); failed to ensure that quality assessment programs were established (refer to D6094); and failed to ensure the competency of 3 of 3 personnel performing cytology processing (refer to D6103). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities

	to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, review of laboratory records, observation and interviews it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of Facility A, to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D5203, D5209, D5403, D5629, D5633, D5637, D5641, D5645, D5659 and D5805
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, review of laboratory records, observation, and interviews it was determined that the Laboratory Director failed to ensure that quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur. Cross refer to D5291, D5891
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of laboratory polices and procedures, laboratory records and interview it was determined that the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain competency of three of three personnel performing cytology processing. Cross refer to D5209 Findings include: 1. The Survey Team requested and Facility A failed to provide written policies and procedures to describe the laboratory's process for assessing the competency of one of one Staff performing cytology processing. - Staff A 2. The Survey Team reviewed competency assessment records for Staff A. There were no policies and procedures to describe how the competency of Staff A would be assessed. 3. During an interview on October 16, 2018 at 2:05 PM, the Laboratory Director /Technical Supervisor A confirmed these findings.

D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview it was determined that Technical Supervisor A failed to establish individual workload limits and to reassess the workload limits at least every six months for three of three Technical Supervisors in 2016, 2017 and to the date of the survey in 2018. Cross Refer to D5633 and D5637
D6133	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6) In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2), if responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview it was determined that three of three Technical Supervisors failed to document the number of slides and the time spent examining slides in each 24-hour period in 2016, 2017 and to the date of the survey in 2018. Cross refer to D5645
D9999	By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.