DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 06/14/2018 FORM APPROVED OMB NO. 0938-0391

MANE OF PROVIDER OR SUPPLIER REPRODUCTIVE HEALTH SERVICES SUMMARY STATEMENT OF DEPCEMBENS PRESS (CAST) STATE, 2P CODE ##1 SOUTH PERRY STREET MONTGOMERY, AL 35104 CAST) DEPCEMBENT OF DEPCEMBENS (CAST) STREET ADDRESS, CITY, STATE, 2P CODE ##1 SOUTH PERRY STREET MONTGOMERY, AL 35104 CAST) DEPCEMBENT OF DEPCEMBENS (CAST) STREET ADDRESS, CITY, STATE, 2P CODE ##1 SOUTH PERRY STREET MONTGOMERY, AL 35104 PRESS (CAST) STREET ADDRESS, CITY, STATE, 2P CODE ##1 SOUTH PERRY STREET MONTGOMERY, AL 35104 PRESS (CAST) STREET ADDRESS, CITY, STATE, 2P CODE ##1 SOUTH PERRY STREET MONTGOMERY, AL 35104 PRESS (CAST) STREET ADDRESS, CITY, STATE, 2P CODE ##1 SOUTH PERRY STREET MONTGOMERY, AL 35104 PRESS (CAST) STREET ADDRESS, CITY, STATE, 2P CODE ##1 SOUTH PERRY STREET MONTGOMERY, AL 35104 PRESS (CAST) STREET ADDRESS, CITY, STATE, 2P CODE ##1 SOUTH PERRY STREET MONTGOMERY, AL 35104 PRESS (CAST) STREET MONTGOMERY, AL 35104 PRESS (C	STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	` ´	JITIPLE CONSTRUCTION DING		(X3) DATE SURVEY COMPLETED		
SUMMARY STATEMENT OF DEFICIENCIES SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REQUILATORY OR LSC IDENTIFYING INFORMATION) PRETIX TAG PROVIDERS FLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REQUILATORY OR LSC IDENTIFYING INFORMATION) PRETIX TAG PROVIDERS PLAN OF CORRECTION (EACH OBSERCTIVE ACTION SOULD BE COMPLETION DATE OF CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) DOES OF COMPLETION DATE OF CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY; The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing percords and an interview with the facility owner (Aboratory failed to ensure proficiency testing specimens were tested only the same number of times patient specimens are routinely tested. The findings include: 1. A review of the proficiency testing records revealed the attestation statements for all three events in 2013 and 2014 were signed by multiple testing personnel (three to five testing personnel), indicating all specimens were tested by all personnel. 2. In an interview on 2/12/2015 at 10:00 AM, the (b)(6)(b)(7)/(c) stated all testing personnel test all the proficiency testing samples, prior to submission of the results. The (b)(6)(b)(7)/(c) (b)(6)(b)(7)/(c) (d)(b)(6)(b)(7)/(c) (d)(b)(6)(b)(7)/(c) (d)(b)(6)(b)(7)/(c) (d)(b)(6)(b)(7)/(c) (d)(b)(6)(b)(7)/(c) (d)(d)(d)(d)(d)(d)(d)(d)(d)(d)(d)(d)(d)(01D0304393	B. WING _			02/	12/2015	
Description Princip					STREET ADDRESS, CITY, STATE, ZIP CODE 811 SOUTH PERRY STREET				
CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) proficiency testing records and an interview with the facility owner (laboratory manager), it was determined the laboratory failed to ensure proficiency testing specimens were tested only the same number of times patient specimens are routinely tested. The findings include: 1. A review of the proficiency testing records revealed the attestation statements for all three events in 2013 and 2014 were signed by multiple testing personnel (three to five testing personnel), indicating all specimens were tested by all personnel. 2. In an interview on 2/12/2015 at 10:00 AM, the (b)(6)(b)(7)(c) stated all testing personnel test all the proficiency testing samples, prior to submission of the results. The(b)(6)(b)(7)(c) (b)(6)(b)(7)(d)urther stated patient samples are not routinely tested this number of times and by multiple testing personnel. (b)(6)(b)(7)(c)	PREFIX	(EACH DEFICIENCY MUST BE PRECEDED BY FULL		PREFIX	((EACH CORRECTIVE ACTION SHOULD E CROSS-REFERENCED TO THE APPROPRI		COMPLETION	
(b)(6)(b)(7)(c) stated all testing personnel test all the proficiency testing samples, prior to submission of the results. The(b)(6)(b)(7)(c) (b)(6)(b)(7)(d)urther stated patient samples are not routinely tested this number of times and by multiple testing personnel. (b)(6)(b)(7)(c)	D2010	CFR(s): 493.801(b)(2 The laboratory must to number of times that samples. This STANDARD is represented by the same of the same of the same specimens are routing include: 1. A review of the profession of the profession of the same specimens are routing include: 1. A review of the profession of the same specimens are routing include: 1. A review of the profession of the same specimens are routing include: 1. A review of the profession of the same specimens are routing include: 1. A review of the profession of the same specimens are routing include: 1. A review of the profession of the same specimens are routing include: 1. A review of the profession of the same specimens are routing include: 1. A review of the profession of the same specimens are routing include:	est samples the same it routinely tests patient not met as evidenced by: f API (American Proficiency esting records and an lity owner (laboratory emined the laboratory failed testing specimens were number of times patient ely tested. The findings officiency testing records on statements for all three on the personnel,	D20	010	SELIOLINOT)		3/18/15	
ABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE		(b)(6)(b)(7)(c) s test all the proficiency submission of the res b)(6)(b)(7)(cfurther state routinely tested this n multiple testing perso (b)(6)(b)(7)(cfurther state routinely tested this n multiple testing perso	tated all testing personnel testing samples, prior to ults. The(b)(6)(b)(7)(c) and patient samples are not umber of times and by nnel. 7)(c) cation Surveyor						

03/18/2015

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	1 ' '	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED			
		01D0304393	B. WING			02/	14/2017		
NAME OF PROVIDER OR SUPPLIER REPRODUCTIVE HEALTH SERVICES				STREET ADDRESS, CITY, STATE, ZIP CODE 811 SOUTH PERRY STREET MONTGOMERY, AL 36104					
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFI TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD B CROSS-REFERENCED TO THE APPROPRI DEFICIENCY)		(X5) COMPLETION DATE		
	The (b)(6)(b)(7)(c) overall operation and laboratory, including who are competent to and record and report accurate, and proficie compliance with the a (e) The laboratory dir (e)(11) Ensure that proper specimens, all persone ducation and experiappropriate training for the services offered, they can perform all the provide and report accurate and report accurate and report accurate. This STANDARD is an an accurate with the determined the (b) ensure one of three the with the appropriate et allowing the persone complexity testing. The findings include: 1. During an interview (b)(6)(b)(7)(c) and education. Testing Performs (b)(6)(b)(7)(c) and the laboration (b)(6)(6)(6)(6)(is responsible for the administration of the the employment of personnel operform test procedures, it test results promptly, ently and for assuring applicable regulations. ector mustance of the appropriate ence, receive the part the type and complexity of and have demonstrated that esting operations reliably to curate results. Into the metian evidenced by: If personnel records and an (b)(6)(b)(7)(c) it was (6)(b)(7)(c) failed to esting personnel presented educational credentials, prior nel to perform moderate W on 2/14/17 at 9:05 AM, the stated she had trained an anot yet provided evidence of ersonnel #3 (TP #3), who (b)(6)(b)(7)(c) atory. According to the the testing privileges of TP		029	TITLE		3/2/17 (X6) DATE		

03/02/2017

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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		01D0304393	B. WING _			02/14/2017			
NAME OF PROVIDER OR SUPPLIER REPRODUCTIVE HEALTH SERVICES				STREET ADDRESS, CITY, STATE, ZIP CODE 811 SOUTH PERRY STREET MONTGOMERY, AL 36104					
(X4) ID PREFIX TAG	(EACH DEFICIENC)	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL .SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN O X (EACH CORRECTIVE AC CROSS-REFERENCED TO DEFICIEN	TION SHOULD BE THE APPROPRIATE	(X5) COMPLETION DATE			
D6029	the regulation that the must be verified, prior test patient samples. 2. A review of TP #3 no educational creder personnel. TP #3's d	e educational credentials to allowing an employee to 's personnel file confirmed ntials were filed for this ate of hire was listed as on date(d)(6)(b)(7)(a)nd initial mpleted(b)(6)(b)(7)(c) (c)	D60	029					

3348342098 p.2 DEPARTMENT OF HEALTH AND HUMAN SERVICES PRINTED: 02/17/2017 CENTERS FOR MEDICARE & MEDICAID SERVICES FORM APPROVED OMB NO. 0938-0391 STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION AND PLAN OF CORRECTION (X3) DATE SURVEY IDENTIFICATION NUMBER: A. BUILDING COMPLETED 01D0304393 B. WING 02/14/2017 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE REPRODUCTIVE HEALTH SERVICES 811 SOUTH PERRY STREET MONTGOMERY, AL 36104 SUMMARY STATEMENT OF DEFICIENCIES (X4) ID ID PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (X5) COMPLETION DATE PREFIX (EACH CORRECTIVE ACTION SHOULD BE REGULATORY OR LSC IDENTIFYING INFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE TAG DEFICIENCY) 493.1407(e)(11) LABORATORY DIRECTOR D6029 RESPONSIBILITIES 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, and record and report test results promptly. accurate, and proficiently and for assuring 493.1407(e)(11) This was immediately corrected compliance with the applicable regulations. and Testing Personnel #3 has not performed any (e) The laboratory director mustfurther testing. Testing Personnel will not be (e)(11) Ensure that prior to testing patients' performing any further testing at all. Testing specimens, all personnel have the appropriate Personne I#3 failed to provide the necessary education and experience, receive the education documentation. appropriate training for the type and complexity of the services offered, and have demonstrated that No Testing Personnel will be trained without the they can perform all testing operations reliably to necessary education documentation required by provide and report accurate results. CLIA in place and reviewed by the Director and no testing will be done prior to said documentation. This STANDARD is not met as evidenced by: Based on a review of personnel records and an An additional check of this credentialing will be interview with the (b)(6)(b)(7)(c)it was added to the initial training and annual certification determined the (b)(6)(b)(7)(c)failed to ensure one of three testing personnel presented evaluation of lab personnel. 3/2/17 with the appropriate educational credentials, prior to allowing the personnel to perform moderate complexity testing. The findings include: 1. During an interview on 2/14/17 at 9:05 AM, the stated she had trained an (b)(6)(b)(7)(c)employee, who had not yet provided evidence of

also stated she understands (b)(6)(b)(7)(c)LABORATORY DIRECTOR'S ON PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

#3 was recently suspended, due to the

education. Testing Personnel #3 (TP #3), who

(b)(6)(b)(7)(c)(b)(6)(b)(7)(c)at the laboratory. According to the

educational credentials not being provided. The

au Ust Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued

FORM CMS-2567(02-99) Previous Versions Obsolete

performs

(b)(6)(b)(7)(c)

Event ID: 3TFK11

works

, the testing privileges of TP

Facility ID: 01D0304393

TITLE

If continuation sheet Page 1 of 2

(XS) DATE

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) ML A. BUIL		CONSTRUCTION	OMB NO. 0938-039 (X3) DATE SURVEY COMPLETED	
01D0304393		B. WING					
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D6029	test patient samples 2. A review of TP # no educational cred personnel. TP #3's 7/15/15 with oriental	the educational credentials or to allowing an employee to s. t3's personnel file confirmed entials were filed for this date of hire was listed as tion dated 7/15/15 and initial ompleted 10/25/1\(\theta\)(6)(b)(7)(c)	D6	029	DEFICIENCY)		
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