UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

NADEZDA STEELE-WARRICK, individually and on behalf of all others similarly situated,	
Plaintiff,	**ORDER**
	19 Civ. 6558 (VMS)
-against-	
MICROGENICS CORPORATION and THERMO FISHER SCIENTIFIC, INC.,	
Defendants.	

Vera M. Scanlon, United States Magistrate Judge:

Plaintiff Nadezda Steele-Warrick, individually and on behalf of all others similarly situated ("Plaintiff"), brings this action against Defendants Microgenics Corporation ("Microgenics") and Thermo Fisher Scientific, Inc. ("Thermo Fisher," together, "Defendants") alleging a negligence claim under New York law. See First Amended Complaint ("FAC"), ECF No. 31. In summary, Plaintiff alleges that while she was in Department of Corrections and Community Supervision ("DOCCS") custody, Defendants failed to adhere to relevant professional standards in their performance of their contractual obligations in connection with DOCCS's inmate urinalysis drug testing program to provide urinalysis machines, products and related training, support, maintenance and testimony services. See id.

Plaintiff claims that as a result of Defendants' negligence, she and thousands of other inmates suffered undeserved discipline on the basis of false positive drug test reports. See id. Plaintiff brings her negligence claim on her own behalf and on behalf of a similarly situated class of inmates. See id.

Before the Court are Defendants' motions to dismiss for failure to state a claim and to strike Plaintiff's class allegations. See ECF Nos. 47, 47-1, 47-2, 48, 48-1, 48-2. For the reasons that

follow, the Court denies Defendants' motions.

I. Facts

The following statement of facts is drawn in the first instance from Plaintiff's operative complaint unless otherwise noted.[1] See FAC, passim.

a. Defendants And IPUA

Defendant Thermo Fisher is a Delaware company that is based in Waltham, Massachusetts. See FAC ¶ 10. Defendant Thermo Fisher manufactures and markets drug-testing machines known as Indiko Plus urinalysis analyzers (hereinafter "IPUA") and assays or reagents used with those machines to test a subject's urine for illicit substances. See FAC ¶¶ 10, 23, 24. As relevant here, after a subject's urine is mixed with reagents, the IPUA interprets the reaction for the presence or absence of illicit substances such as buprenorphine, synthetic cannabinoids, opiates and tetrahydrocannabinol ("THC") according to cutoff detection levels specific to those substances as predetermined by DOCCS and/or the United States Substance Abuse and Mental Health Services Administration ("SAMHSA"). See FAC ¶ 43; Exh. 1 at 80,

[1] Defendants' Exhibits 1 through 6 were annexed to the Declaration of their counsel Nathan J. Marcusen ("Marcusen Decl"). See ECF No. 48-2. Because the Marcusen Declaration attests that Defendants' Exhibits 1 through 6 are true and accurate copies of what they purport to be, the Court hereinafter cites to Defendants' numbered exhibits without further reference to counsel's declaration.

119[2]; Exh. 4.[3]

According to Plaintiff, Defendant Thermo Fisher is responsible for all Federal Drug Administration ("FDA") submissions relating to IPUA machine and assays. See FAC ¶¶ 10, 24. In response, Defendant Thermo Fisher asks the Court to take judicial notice of two FDA records summarizing the agency's review of the IPUA machine and buprenorphine assays—including those pursuant to Clinical and Laboratory Standards Institute ("CLSI") standards and guidelines—pursuant to applications that were made by a Thermo Fisher entity with a slightly different name and by Defendant Microgenics, respectively. See Exh. 5; Exh. 6.[4]

Defendant Thermo Fisher is the parent company to and wholly owns Defendant

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[2] Defendants submitted the contract between DOCCS and Defendant Microgenics dated October 2, 2018, and at least some of its incorporated appendices—including DOCCS's Invitation for Bids and Defendant Microgenics's bid response, see Sections I.c-d—in connection with its instant motion because they argue that the Plaintiff's FAC incorporated it by reference. See Exh. 1. Insofar as Plaintiff does not object, the Court considers the Contract as it finds relevant. See Interpharm, Inc. v. Wells Fargo Bank, Nat'l Ass'n, 655 F.3d 136, 141 (2d Cir. 2011) ("Where . . . certain contracts are integral to the complaint, we [] consider those documents."); Global Network Commc'ns., Inc. v. City of New York, 458 F.3d 150 (2d Cir. 2006) (noting that documents are integral to a complaint where the plaintiff relied on the terms and effect of the documents in drafting the complaint (quoting Chambers v. Time Warner, Inc., 282 F.3d 147, 153 (2d Cir.2002) (internal quotation marks omitted)).

[3] Defendants submitted three DOCCS directives as exhibits in connection with the instant motion, which they argue may be the subject of judicial notice at the Rule 12 stage. See ECF No. 48-1 at 4 n.3 (citing Young v. Corcoran, 164 F. Supp. 3d 419, 421 (W.D.N.Y. 2016)). Plaintiff does not object, and the Court considers the DOCCS directives as it finds relevant.

[4] Defendants argue that the Court can take judicial notice of these publicly available FDA market-clearance documents on the instant motion. See ECF No. 48-1 at 5 n.4 (citing Crespo v. S.C. Johnson & Son, Inc., 394 F. Supp. 3d 260, 266 n.3 (E.D.N.Y. 2019) (taking judicial notice of documents on EPA's website, including records pertaining to the subject product's EPA registration); Tierney v. AGA Med. Corp., No. 11 Civ. 3098 (RGK), 2011 WL 7400469, at *4 (D. Neb. Nov. 18, 2011) (taking judicial notice of "Instructions for Use" documents publicly available on FDA's website where said documents contained warnings against same adverse reaction suffered by the plaintiff)). Plaintiff does not object, and the Court considers the FDA records as relevant.

Microgenics, which is a Delaware company based in Fremont, California. See FAC ¶¶ 9-10. Defendant Microgenics specializes in the development, manufacture, marketing and sale of products relating to clinical diagnostics. See FAC ¶ 9. Defendant Microgenics is among various medical distributors of Defendant Thermo Fisher's IPUA across the United States. See FAC ¶ 25.

Plaintiff alleges that, pursuant to Defendants' own standards as the manufacturers of IPUA machines and products, the accuracy of any positive drug test results obtained through IPUA urinalysis is to be verified by a confirmatory test using gas chromatography or some other method. See FAC ¶¶ 28-41; id. ¶¶ 7, 34, 43-44, 77. This standard is in place in order to eliminate a urinalysis test risk of false positives due to reagents' cross-reactivity potential, which refers to when reagent reactions are triggered by lawful medications or other non-illicit substances in urine. See FAC ¶¶ 28-41; id. ¶¶ 7, 34, 43-44, 77; ECF No. 48-1 at 4 (citing to Lahey v. Kelly, 71 N.Y. 2d 135, 139 (N.Y. 1987) (discussing, among other things, challenges to the false positive immunoassay scans on the basis of cross-reactivity with medications)); id. (citing Peranzo v. Coughlin, 608 F. Supp. 1504, 1514 (S.D.N.Y. 1985) (same)); id. at 21 n.8 (noting the defendants' understanding of the plaintiff's allegations to be about IPUA urinalysis test scans providing false positive as a result of reagents' cross-reactivity issues with the non-illicit substances it was meant to detect). Stated differently by way of example, the problem of "cross-reactivity" in drug screens occurs where "innocent items like poppy seeds will be confused with illicit substances." Coleman v. Town of Hempstead, 30 F. Supp. 2d 356, 365 (E.D.N.Y. 1999) (citation omitted); see Santiago v. Greyhound Lines, Inc., 956 F. Supp. 144, 150 (N.D.N.Y. 1997) ("Drug screens are plagued by the problems of 'cross-reactivity'—namely, the familiar concern that metabolites of benign consumables, like poppy seed muffins, will be

confused with metabolites of illicit substances[.]"); Frantz v. Venettozzi, 146 A.D.3d 1254, 1255 (3d Dep't 2017) (noting that urinalysis testing equipment manual contained at least one page pertaining to cross-reactivity issues).

b. DOCCS's Inmate Urinalysis Program

Consistent with Plaintiff's allegation that Defendants' manufacturer standards require that confirmatory testing verify any positive result obtained by their IPUA urinalysis, see FAC ¶ 34, Defendants state that DOCCS has known for nearly 40 years that immunoassay manufacturers recommend that positive urinalysis drug-screen results be confirmed by an alternative scientific method, such as gas chromatography-mass spectrometry, see ECF No. 48-1 at 4 (citing Peranzo, 608 F. Supp. at 1514). As relevant here, assuming that a urinalysis screen is generally reliable, the confirmatory-test recommendation is meant to minimize any false-positive margin of error, however small, inherent in relying on urinalysis testing alone. See Peranzo, 608 F. Supp. at 1514. Even still, DOCCS's inmate urinalysis testing has at all relevant times employed reagent test urinalysis scans (also known as the "immunoassay" method) alone without confirmatory testing "to verify whether or not an inmate has used drugs." N.Y. Comp. Codes R. & Regs. tit. 7 § 1020.1; see Exh. 1 at 80; Exh. 4 at 189-92. Evidence that DOCCS's has intentionally elected not to make confirmatory testing a part of its inmate urinalysis program is the fact that DOCCS has made a different choice as to other drug testing programs, such as DOCCS's parolee and employee drug testing programs. Compare Exhs. 2-3 (DOCCS directives governing parolee and employee drug testing) with Exh. 4 (DOCCS directive governing inmate urinalysis program).

With respect to DOCCS's inmate urinalysis testing program, New York regulation and DOCCS Directive 4937 outline "the procedures to be followed by each [DOCCS] facility in the

administration of inmate urinalysis testing." N.Y. Comp. Codes R. & Regs. tit. 7 § 1020.2; see Exh. 4. For example, at the time an inmate's urine is collected, all DOCCS personnel handling the specimen must be identified on a DOCCS chain of custody form and inquiry must be made as to whether the inmate "has been taking any medication in the past month," N.Y. Comp. Codes R. & Regs. tit. 7 § 1020.4(d)(2); see Exh. 4. "If the facility has [a] urinalysis testing apparatus . . . [t]he individual performing the urinalysis testing shall have been appropriately trained in the use of the testing apparatus and shall precisely follow procedures recommended by the manufacturer for the operation of the testing apparatus." N.Y. Comp. Codes R. & Regs. tit. 7 § 1020.4(f)(1)(iii); see Exh. 4. DOCCS facilities are required to enroll in the Urine Toxicology Testing Service of the American Association of Bioanalysts ("AAB"). See N.Y. Comp. Codes R. & Regs. tit. 7 § 1020.7 ("The facility shall enroll in the Urine Toxicology Proficiency Testing Service of the American Association of Bioanalysts, 205 West Levee, Brownsville, TX 78520."); see N.Y. Comp. Codes R. & Regs. tit. 7 § 1020.4(f)(1)(iii); Exh. 4. This requirement may suggest that the DOCCS standard for an "appropriately trained" individual's urinalysis testing proficiency is determined with reference to that that institution's standards. New York requires that

> [i]f a positive result is obtained on the first test [of the urine specimen provided by the inmate], the procedure followed and the results obtained shall be noted by the operator on the [relevant DOCCS] urinalysis procedure form. A second test shall be performed on the same sample. The results of the second test shall be noted on a second [DOCCS] urinalysis procedure form. If a positive result is obtained from the second test, the individual performing the urinalysis testing shall cause a misbehavior report to be issued. The inmate's copy of the misbehavior report shall be accompanied by the request for urinalysis test form, the urinalysis procedure form, the inmate's printed results produced by the urinalysis testing apparatus for the positive tests and a statement of the scientific principles [hereinafter "Statement of Scientific Principles"] and validity of the testing apparatus [hereinafter "Statement of Testing Apparatus Validity"].

N.Y. Comp. Codes R. & Regs. tit. 7 § 1020.4(f)(1)(iv); Exh. 4 at 187 § IV.G.d (DOCCS

Directive 4937). As to any inmate who receives a positive urine drug screen and who also reported taking medication at the time the sample was obtained, DOCCS must conduct an "inquiry . . . to medical personnel as to what medications the inmate has received in the past month which may lead to a positive result." N.Y. Comp. Codes R. & Regs. tit. 7 § 1020.4(d)(2).

Prior to imposing discipline upon an inmate for drug use based on test results, DOCCS holds a disciplinary hearing. See N.Y. Comp. Codes R. & Regs. tit. 7 § 253.6. At such a hearing, DOCCS may use an inmate's positive urinalysis result as evidence of the inmate's illicit use of the drug indicated by presenting, inter alia, "any printed documents produced by the urinalysis testing apparatus" and the appropriate Statement of Scientific Principles and Validity of the Testing Apparatus "if the facility has urinalysis testing apparatus." N.Y. Comp. Codes R. & Regs. tit. 7 § 1020.5(a)(1). The inmate also has the right to submit evidence at such a disciplinary hearing, including evidence explaining the positive drug screen and challenging the drug screen procedures. See N.Y. Comp. Codes R. & Regs. tit. 7 § 253.6(c); Lahey, 71 N.Y.2d at 144.

c. DOCCS Invitation For Bids

In 2018, DOCCS issued an Invitation for Bids No. 2018-06 ("IFB") seeking to award a contract for the provision of urinalysis machines and products as well as training, support, maintenance and testimony services. See Exh. 1 at 80-82. According to the IFB, the DOCCS annually performed many thousands of urine scans at its 52 correctional facilities using five reagent tests and a "normal" one of these screened for (i) buprenorphine at a 5ng/mL cutoff, (ii) synthetic cannabinoids at a 10 ng/mL cutoff, (iii) opiates at a 300 ng/mL cutoff and (iv) THC at a 50 ng/mL cutoff. See Exh. 1 at 80. In furtherance of these activities, the IFB sought a bidder willing and able to:

- Deliver and install new bench top urinalysis analyzer machines in the quantities stated and to the locations directed on timeframes needed. See Exh. 1 at 80.

- Supply all reagents relating to DOCCS's urinalysis testing according to required terms. Among other things, the bidder's satisfaction of this requirement entailed its designation of an official contact for DOCCS for related issues and it was required to develop the method by which DOCCS would approve its facilities' orders. See id.

- Provide related urinalysis testing training services. Among other things, the bidder's satisfaction of this requirement entailed its training and certification of five DOCCS staff members as proficient urinalysis testers at each of the agency's 52 facilities (i.e., the training and certification of 260 DOCCS staff). The bidder's certifications of tester proficiency was required to be pursuant to minimum standards set by the bidder itself. In addition, the bidder was required to train and certify "masters" at nine DOCCS hubs to allow these masters to themselves train and certify testers themselves. See id. at 80-81.

- Provide related support and maintenance services in connection with the analyzer machines. These support and maintenance services included, but were not limited to: (i) urinalyzer operator manuals; (ii) 24/7 telephone support for analyzer issues; (iii) at least two annual visits to each of the 52 DOCCS facilities for preventative analyzer maintenance; (iv) 24-hour response time for required/requested analyzer maintenance; (v) 48-hour response time for complete replacement of an analyzer due to failure; and (vi) user feedback procedures. See id.

- Related testimony services requiring the bidder to provide witnesses at DOCCS administrative hearings to testify about urinalysis analyzer machine operation, calibration, maintenance, procedures and cross-reactivity. See id. at 82.

The IFB also required that all bidders agree to adhere to all federal and state laws and regulations in providing these products and services pursuant to any contract awarded. See Exh. 1 at 78.

d. Defendant Microgenics's Bid

Defendant Microgenics submitted a bid in response to DOCCS's IFB representing that it was willing and able to meet all of the IFB's specifications.[5] See Exh. 1 at 114-158. In relevant

[5] Although Defendants have argued that Defendant Microgenics, and not Defendant Thermo Fisher, made this bid in response to DOCCS's IFB and that Defendant Microgenics, and not Defendant Thermo Fisher, entered into a contract with DOCCS as a result, the Court will refer to Defendant Microgenics's bid and Contract as Defendants' bid and contract throughout this Order given its finding that Plaintiff's FAC contains sufficient allegations against Defendant Thermo Fisher as a Defendant. See Section III.d, infra.

part, Defendant Microgenics specifically represented that it could and would:

- Supply and deliver its platform of IPUA urinalysis analyzer machines, reagents and other products in satisfaction of the IFB's requirements with respect to the drugs of abuse and their cutoffs identified by the IFP (buprenorphine, synthetic cannabinoids, opiates and THC), and stated that the IPUA's measurements would meet or exceed SAMHSA cutoff detection guidelines over the life of any contract awarded through the use of reagents cleared by the FDA. See Exh. 1 at 117, 119;

- Provide training services for DOCCS staff and certify them as proficient testers according to self-determined minimum standards and with attention paid to issues including those pertaining to "cross-reactivity." See id. at 118

- Provide testimony at disciplinary hearings covering questions about the platform of IPUA machines, products and services including those pertaining to "operation, calibration, maintenance, procedures, reagents and cross-reactivity." See id. at 119.

Plaintiff alleges that while negotiating a contract with DOCCS, Defendants knew but did not disclose to DOCCS that Defendants' standards for the IPUA as its manufacturer state that the machines should be used as an initial screen only, with an outside laboratory's confirmatory testing using gas chromatography or another method required to verify a reliable positive result. See FAC ¶¶ 34, 40-41.

As relevant to the instant motion, Defendant Microgenics's bid made extensive references to Defendant Thermo Fisher. See Exh. 1 at 114-158. For example, it began with a cover letter that (i) was on letterhead calling Defendant Microgenics "A Thermo Fisher Scientific Company;" (ii) contained multiple references to Thermo Fisher's involvement in the provision of "hardware," "reagents + consumables shipments," "training" and "testimony" offered in connection with the bid; (iii) represented that a sales representative and regional sales manager with Thermo Fisher email addresses were authorized to negotiate on behalf of "Microgenics A Part of Thermo Fisher;" and (iv) included Thermo Fisher's Web site address. See FAC ¶¶ 14-18; Exh. 1 at 114-120; id. at 148-49 (bid cost sheet). Defendant Microgenics's bid also included a bid signature page listing (i) "d/b/a Thermo Fisher Scientific" in the field for

"D/B/A – Doing Business As (if applicable)"; (ii) a Thermo Fisher email address in the field for "E-mail Address"; and (iii) Thermo Fisher's Web site address in the field for "Company Web Site." Exh. 1 at 122; see FAC ¶ 21. Defendant Microgenics's bid provided a Thermo Fisher email address in its responses to IFB questions about the person to contact about contract orders or after-hours and holiday emergencies, see Exh. 1 at 151, and included marketing materials for Defendant Thermo Fisher urinalysis systems and literature for "Thermo Fisher Microgenics Reagent information," see See FAC ¶¶ 19-20.

According to Plaintiff, at the time of the bid and contract negotiation process, Defendants' own standards as IPUA's manufacturers were to recommend that it be used as an initial drug screen only, and that any positive result should be verified by a confirmatory test such as gas chromatography or another method to ensure its accuracy and reliability. See FAC ¶¶ 24, 33-35, 40. Plaintiff alleges that Defendants failed to inform DOCCS of this at the time of their bid submission or contract negotiation. See FAC ¶¶ 35-36, 40.

e. The Contract

In June 2018, DOCCS awarded Defendant Microgenics Contract No. CC1614458 in connection with the DOCCS IFB and Defendant Microgenics's related bid. See FAC ¶ 22; Exh. 1 at 5-22; id. at 5, 22. The Court will hereinafter refer to Contract No. CC1614458—comprised of the parties' original June 2018 Agreement and a later October 2018 Agreement Amendment that were then together approved by the Comptroller of the State of New York —as the "Contract." See Exh. 1 at 4-19 (Agreement); id. at 20-22 (Agreement Amendment). Insofar as the Contract incorporated the DOCCS's IFB and Defendant Microgenics's bid response by reference, it required Defendant Microgenics to satisfy the DOCCS's IFB requirements as discussed, supra, in Sections I.c-d. See Exh. 1 at 13 § IX-X. In other words, Defendant

Microgenics was required to provide:

- Its platform of IPUA urinalysis analyzer machines, reagents and other products at 52 DOCCS facilities with the capacity to scan urine for buprenorphine, synthetic cannaboids, opiates or THC at or in excess of SAMHSA's cutoff detection guidelines using FDA-cleared reagents, see FAC ¶¶ 2, 9, 22, 26, 30; Exh. 1 at 80, 117, 119; id. at 114-158;

- Related training services which, among other things, would address urinalysis cross-reactivity issues in connection with the certification of DOCCS staff as proficient testers according to a minimum standard that Defendant Microgenics agreed it would set, see FAC ¶¶ 2, 9, 22, 26; Exh. 1 at 80-81, 118; id. at 114-158;

- Related support, installation and maintenance services so that the IPUA urinalysis machines would be "substantially uninterrupted or error-free in operation" and in compliance with applicable manufacturer's specifications and legal standards to ensure accurate and reliable results, see FAC ¶¶ 2-3, 7, 9, 22, 26, 30, which Defendant Microgenics warranted to achieve through, inter alia: (i) 24/7 telephone support for IPUA issues; (ii) at least two annual visits to each of the 52 DOCCS facilities for preventative IPUA maintenance; (iii) 24-hour response time for required/requested IPUA maintenance; and (iv) 48-hour response time for complete replacement of an analyzer due to failure, see FAC ¶¶ 2, 9, 22, 27; Exh. 1 at 81, 114-158; and

- Related testimony services at disciplinary hearings arising from an inmate's receipt of a positive IPUA urine screen, including testimony covering questions about the platform of IPUA machines, products and services including those pertaining to "operation, calibration, maintenance, procedures, reagents and cross-reactivity," see FAC ¶¶ 28-29; Exh. 1 at 82, 119.

The Contract also required Defendant Microgenics to replace any test kits manufactured within six months that DOCCS is unable to use within 24 months of its manufacture, in light of the test kits' 6- to 24-month shelf life. See Exh. 1 at 21.

In the event that Defendant Microgenics "fail[ed] to comply with the terms and conditions of [the Contract] and/or with any laws, rules, regulations, policies or procedures affecting [the Contract,]" the Contract gave DOCCS the right to terminate the Contract for cause immediately upon written notice to Defendant Microgenics. Id. at 9 § IV.B. As relevant here, the Contract required Defendant Microgenics to hold the People of the State of New York and DOCCS harmless with respect to all liabilities arising out of any third-party claim in any way

connected with Defendants Microgenics's performance of the Contract "including negligence, active or passive or improper conduct of the Contractor, its officers, agents . . . or employees[.]" Id. at 17 § XVI.g.

As relevant to the instant motion, Carol Bowers executed the Agreement on behalf of Defendant Microgenics and, in that document, Ms. Bowers (i) noted that she was Defendant Thermo Fisher's Senior Finance Director and Defendant Microgenics's Chief Operating Officer; and (ii) that Defendants Thermo Fisher and Microgenics were "the corporation described" in the Agreement. Exh. 1 at 5. In September 2018, DOCCS delivered an Agreement Amendment to "Microgenics Corp/Thermo Fisher Scientific" for execution and incorporation into the overall and which, once achieved in October 2018, became part of Contract No. CC161458. See FAC ¶¶ 10, 31; Exh. 1 at 21-22.

f. Statement Of Scientific Principles And Validity Of Testing Apparatus

On December 27, 2018, DOCCS revised its Directive 4937 pertaining to procedures for inmate urinalysis testing. See Exh. 4. In relevant part, an appendix to the revised Directive 4937 contained the Statement of Scientific Principles and Validity of Testing Apparatus that inmates were given in the event they were served a misbehavior report after a positive IPUA scan pursuant to DOCCS's inmate urinalysis testing (hereinafter "the Statement"). See Exh. 4 at 189-192, App. A.

The Statement describes the apparatus and the test itself. For example, the apparatus uses reagents to analyze urine for drugs of abuse. See id. at 189. Urine samples are mixed with two reagents, whereupon "[p]hotometric absorbance readings are taken on reagent reactions[,]" and "[t]he system computer interprets operator input, processes reagent data, and interprets results." Id. "The reaction rate of the cut-off calibrator serves as the reference point[,]" and "[a] sample is

considered positive if its reaction rate is equal to or greater than that of the cut-off calibrator[.]" Id. (emphasis in original). The Statement lists certain critical parameters of use which include, inter alia: (i) that reagents must be stored at specific temperatures, and (ii) that the performance of the instrument and reagents must be periodically checked, including with daily procedures to ensure the system's proper operation through calibration accuracy and sample testing. See id. at 190. The system's reliability is also addressed by the Statement, which called it "among the most consistently accurate drug testing methods in current use," employed by various federal and state agencies, hospitals, drug courts and treatment programs. Id. at 190-91. In addition, the Statement cited to a study evaluating IPUA's precision and accuracy as well as "sensitivity and specificity" at required medical and psychological assessment ("MPA") abstinence-control cutoffs. Id. at 191. The study found IPUA's specificity and sensitivity to the drugs of abuse evaluated to range from 91 to 100% and recommended it as a method for abstinence control drug screening. See id.

g. Defendants Fail To Disclose Or Take Action To Correct IPUA Cross-Reactivity Issues That Degraded The Accuracy And Reliability Of Positive Urine Scan Results

Defendants began providing their platform of IPUA machines, products and services to DOCCS in late 2018 or early 2019. See FAC ¶ 32; Exh. 1 at 6 § I (stating that the Agreement was intended to commence September 1, 2018). According to Plaintiff, Defendants' own manufacturers' standards were that IPUA positive screens should be verified by a confirmatory test such as gas chromatography to ensure its accuracy and reliability, but that Defendants did not disclose this requirement as part of their training, support or testimony services. See FAC ¶¶ 24, 33-38, 40. Further, in Defendants' provision of their platform of IPUA machines, products and services for DOCCS's inmate urinalysis testing, they became aware that the IPUA had a

cross-reactivity problem, meaning that the system was falsely reporting innocent substances in urine as illicit substances, after inmates began to report an atypically high numbers of false IPUA positive scans. See FAC ¶¶ 39, 42-45. Plaintiff alleges that Defendants unreasonably failed to take corrective action to ensure that their products and services were used in accordance with applicable standards even though their manufacturing, training, support, maintenance and testimonial roles put them in full control over the nature of the use. See FAC ¶¶ 39, 42-45. As a result, Defendants knowingly allowed inmates to be disciplined on the basis of positive IPUA scans without disclosing that the test was suffering cross-reactivity issues such that DOCCS's understandings about its accuracy and reliability had been compromised. See FAC ¶¶ 39, 42-45.

h. Plaintiff Is Among Thousands Of Inmates Who Allegedly Received A False Positive Urine Screen In 2019 As A Result Of IPUA's Cross-Reactivity Problems

According to Plaintiff, she was among thousands of DOCCS inmates who tested positive for drugs of abuse in 2019 and who were charged and punished even though they did not ingest any illicit substance. See FAC ¶¶ 3-5.

In April 2019, Plaintiff was incarcerated at a DOCCS facility where, as a result of good behavior and after a lengthy application process, she had earned privileges including participation in a program allowing longer family visits. See FAC ¶¶ 54-58. Plaintiff's participation in that latter program required her to submit to pre- and post-visit drug testing. See FAC ¶ 59. After an April 2019 family visit, IPUA falsely reported that Plaintiff's urine test was positive for buprenorphine. See FAC ¶¶ 60-62, 64. As a result, Plaintiff was charged with drug use, lost her privileges and was confined in a disciplinary keeplock cell for 11 days before being found guilty at a hearing on the basis of IPUA test result forms. See FAC ¶¶ 66-67, 78. Among other things, Plaintiff was sentenced to a 30-day loss of her privileges. See FAC ¶¶ 78-81.

Plaintiff completed her sentence in May 2019 and was released before satisfying the 30-day sanction. See FAC ¶¶ 78-81.

In September 2019, Plaintiff learned that the disciplinary drug use finding against her had been overturned because DOCCS had identified IPUA's cross-reactivity issues. See FAC ¶¶ 88-89.

i. DOCCS Reversed All Disciplinary Decisions Based On What It Determined Were Unreliable IPUA Positive Results, Terminated The Contract And Sued Defendants Microgenics And Thermo Fisher

DOCCS ultimately determined that the cross-reactivity issues made positive results generated by IPUA so unreliable that it later reversed every inmate disciplinary decision that had been based upon positive buprenorphine, synthetic cannabinoid, opiate and THC urine scans reported by IPUA urinalysis in 2019. See FAC ¶ 46.

In January 2020, DOCCS terminated its contract with Defendants for cause, based on Defendants' failure to comply with the terms and conditions of the DOCCS Contract. See FAC ¶ 48.

In February 2020, the State of New York commenced a lawsuit against Defendants in New York State Supreme Court. See FAC ¶ 50.[6]

The testing failures have also given rise to DOCCS and New York State Inspector General investigations. See FAC ¶ 49.

[6] The Court notes that, in that lawsuit, the State brings causes of action against Defendants including, but not limited to, breach of contract, breach of express warranty, breach of implied warranty, negligence, negligent misrepresentation and contractual indemnity. See New York v. Thermo Fisher Scientific Inc., et al., Index No. 902691-20 (N.Y. Sup. Ct., Albany Cnty. 2020), Docket No. 1 ¶¶ 35-67. Among other things, the State's complaint alleges that it retained the services of a third-party toxicology services vendor to measure the reliability of Defendants' IPUA system tests, and that Defendants' "equipment, products, procedures and services" were inadequate and deficient, [and] failed to operate according to their intended use[.]" See id., Docket No. 1 ¶¶ 26, 28.

j. Proposed Class Action Allegations

Plaintiff invokes Rule 23(b)(3) for her class allegations on behalf of all persons similarly situated. See FAC ¶ 93. As noted, supra, in Section I.h, Plaintiff alleges that she is just one of thousands of individuals who received a false urine scan positive for a drug of abuse and undeserved related charges and punishment as a result of Defendants' actions. See FAC ¶ 94.

II. Procedural History

On November 20, 2019, Plaintiff commenced this action against Defendants, see ECF No. 1, and on March 5, 2020, filed a First Amended Complaint ("FAC") with leave of the Court, see ECF No. 31. According to Plaintiff, inmates were subjected to unreliable urinalysis drug tests and false positive reports as a result of Defendants' negligence. See id. Plaintiff alleges that she was among the inmates who suffered a false positive and undeserved discipline due to the unreliable urinalysis. See id. Plaintiff's action pleads a negligence claim against Defendants on her own behalf, and on behalf of a class of inmates similarly situated. See id.

Defendants move pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(6) to dismiss Plaintiff's negligence claim for failure to state a claim, and pursuant to Rule 12(f) to strike Plaintiff's class allegations. See ECF Nos. 47, 47-1, 47-2, 48, 48-1, 48-2. Plaintiff opposes, see ECF Nos. 47-4, 48-4, and Defendants reply, see ECF Nos. 47-5, 48-5. The Court heard the parties' arguments and considered all submissions. See ECF No. 51.[7]

[7] The submissions and arguments the Court considered also include the parties' submissions and arguments made in connection with pre-motion proceedings. See ECF Nos. 19, 22, 24, 29, 53.

III. Defendants' Rule 12(b)(6) Motions To Dismiss

a. Rule 12(b)(6) Legal Standard

"A complaint will survive a motion to dismiss so long as it 'contain[s] sufficient factual matter . . . to state a claim to relief that is plausible on its face.'" Mandala v. NTT Data, Inc., 975 F.3d 202, 207 (2d Cir. 2020) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). In making that assessment, courts "accept the plaintiff's factual allegations as true and draw all reasonable inferences in her favor." Menaker v. Hofstra Univ., 935 F.3d 20, 30 (2d Cir. 2019). "Specific facts are not necessary[,]" and a plaintiff "need only 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" Erickson v. Pardus, 551 U.S. 89, 93 (2007) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (internal quotations omitted)); Port Dock & Stone Corp. v. Oldcastle Ne., Inv., 207 F.3d 117, 121 (2d Cir. 2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678. Although this plausibility pleading standard is forgiving, a court is not required to credit "legal conclusion[s] couched as . . . factual allegation[s]" or "naked assertions devoid of further factual enhancement." Mandala, 975 F.3d at 207 (quoting Iqbal, 556 U.S. at 678 (internal quotation marks & brackets omitted)).

b. Plaintiff Plausibly Alleged That Defendants Owed Her A Duty Of Care

Under New York law, to establish a claim for negligence, "'a plaintiff must demonstrate (1) a duty owed by the defendant to the plaintiff, (2) a breach thereof, and (3) injury proximately resulting therefrom.'" Pasternack v. Lab. Corp. of Am. Holdings, 27 N.Y.3d 817, 825 (N.Y. 2016) (quoting Solomon v. City of New York, 66 N.Y.2d 1026, 2017 (N.Y. 1985)). "Absent a duty running directly to the injured person there can be no liability in damages, however careless

the conduct or foreseeable the harm." 532 Madison Ave. Gourmet Foods v. Finlandia Ctr., 96 N.Y.2d 280, 289 (N.Y. 2001). "The existence of a duty is a question of law to be decided by the court." McCarthy v. Olin Corp., 119 F.3d 148, 156 (2d Cir. 1997); see Rosenfeld v. Lenich, 370 F. Supp. 3d 335, 358 (E.D.N.Y. 2019) (finding that the duty of care owed by one member of society to another is determined by a court as a matter of law). In weighing whether a duty exists, courts should consider that "[w]henever one person is by circumstances placed in such a position with regard to [a second] that everyone of ordinary sense . . . would at once recognize that if [the second party] did not use ordinary care and skill in his own conduct with regard to the circumstances[,] he would cause danger of injury to the [first] person[,] . . . a duty arises to use ordinary care and skill to avoid such danger." Havas v. Victory Paper Stock Co., 49 N.Y.2d 381, 386 (N.Y. 1980). Courts should also consider that their responsibility in fixing the "orbit of duty" involves limiting "the legal consequences of wrongs to a controllable degree and to protect against crushing exposure to liability." McCarthy, 119 F.3d at 157 (quoting Strauss v. Belle Realty Co., 65 N.Y.2d 399, 402 (N.Y. 1985)). "Although the existence of a contractual relationship by itself generally is not a source of tort liability to third parties," Landon v. Kroll Lab. Specialists, Inc., 22 N.Y.3d 1, 6 (N.Y. 2013), it is not uncommon that "parties outside a contract are permitted to sue for tort damages arising out of negligently performed or omitted contractual duties[,]" Palka v. Servicemaster Mgmt. Servs. Corp., 83 N.Y.2d 579, 586 (N.Y. 1994); see MacPherson v. Buick Motor Co., 217 N.Y. 382, 393 (N.Y. 1916) ("There is nothing anomalous in a rule which imposes upon A, who has contracted with B, a duty to C and D and others according as he knows or does not know that the subject-matter of the contract is intended for their use."). Although New York law holds that a contracting party's duty to an individual outside the contract may arise "where the contracting party, in failing to exercise reasonable care

in the performance of [their] duties, 'launche[s] a force or instrument of harm,'" Landon, 22 N.Y.3d at 6 (quoting Espinal v. Melville Snow Contractors, Inc., 98 2d 136, 140 (N.Y. 2002) (internal quotation marks & citation omitted)); see Moch v. Rensselaer Water Co., 247 N.Y. 160, 168 (N.Y. 1928) ("The query always is whether the putative wrongdoer has advanced to such a point as to have launched a force or instrument of harm, or has stopped where inaction is at most a refusal to become an instrument for good."), "[c]ommon-law experience teaches that duty is not something derived or discerned from an algebraic formula[,]" Palka, 83 N.Y.2d at 585. "Rather, it coalesces from vectored forces including logic, science, weighty competing socioeconomic policies and sometimes contractual assumptions of responsibility. These sources contribute to pinpointing and apportioning of societal risks and to an allocation of burdens of loss and reparation on a fair, prudent basis." Id.

The New York Court of Appeals considered these principles in Landon v. Kroll Laboratory Specialists, Inc., 22 N.Y.3d 1, 4-6 (N.Y. 2013), in which the defendant drug testing laboratory had a contract with a state probation department to test probationers' oral fluid samples for illicit or controlled substances, and the plaintiff alleged that the laboratory falsely reported that he had tested positive for THC in connection with its performance of a toxicology test that failed to adhere to federal and manufacturer cutoff standards and state confirmatory testing requirements. As a result, the government commenced probation-revocation proceedings against the plaintiff. The Landon Court held that despite the absence of a contract between the plaintiff and defendant, the laboratory owed a duty of care to test the plaintiff's biological sample "in keeping with relevant professional standards." Id. at 6-7. In so holding, Landon noted that there were strong public policy considerations for finding a duty under those circumstances because a false positive test result could have profound consequences for the test subject, and it

noted that its decision was "in keeping with that of several other jurisdictions to recognize a duty in similar circumstances," id. at 7 (citing Berry v. Nat'l Med. Servs., 292 Kan. 917, 257 P.3d 287 (Kan. 2011) (finding that the imposition of legal duty to report qualitatively and quantitatively accurate urinalysis drug test results did not violate public policy, a test subject was a foreseeable plaintiff, and harm from allegedly negligent collection and testing of urine samples was foreseeable); Sharpe v. St. Luke's Hosp., 573 Pa. 90, 821 A.2d 1215 (Pa. 2003) (finding that hospital which had collected an employee's urine sample for drug testing pursuant to a contract with her employer owed the employee a duty of reasonable care in collecting and handling her specimen); Duncan v. Afton, Inc., 991 P.2d 739 (Wyo. 1999) (holding that a company hired by an employer to collect urine samples for substance abuse testing program owed a duty of care to employee in processing the specimen)), "as well as that of certain federal courts concluding that New York would recognize such a duty," Landon, 22 N.Y.3d at 7 (citing Drake v. Lab. Corp. of Am. Holdings, No. 02 Civ. 1924 (FB) (RML), 2007 WL 776818, at *2 (E.D.N.Y. Mar. 13, 2007) (denying motion to dismiss negligence claim against defendants contracted or subcontracted to collect, test and analyze employee urine samples, finding that the defendants had duty of care to employee with whom they had no direct contractual relationship to perform the test in non-negligent fashion), aff'd, 417 F. App'x. 84 (2d Cir. 2011); Coleman, 30 F. Supp. 2d at 365 (E.D.N.Y.1999) (same)); see also Shaw v. Psychemedics Corp., 426 S.C. 194, 200 (S.C. 2019) (finding that a drug testing laboratory that contracts with an employer to conduct and evaluate employee drug tests owes a duty of care to the employee test subjects for the purposes of a negligence claim alleging failure to properly and accurately perform the test and report the results).

In Pasternack v. Laboratory Corporation of America Holdings, 27 N.Y.3d 817, 820-21,

826-27 (N.Y. 2016), the New York Court of Appeals declined to find that the defendants—a corporation that had contracted with an airline employer to help administer its pilot drug testing program and its subcontractor lab—owed a duty of care to the plaintiff pilot to comply with certain Department of Transportation ("DOT") drug testing regulations. In Pasternack, Federal Aviation Administration ("FAA") regulations required the plaintiff to submit to random drug testing and, on one such occasion, the plaintiff initially produced an insufficient quantity of urine for testing. See id. at 820-22. In such circumstances, DOT regulations held that the urine specimen collector was required to specifically tell the employee that if he left the collection site before producing the sufficient amount of urine it would be considered a "refusal to test" and reported. See id. at 821. The plaintiff alleged that he left because the defendants negligently failed to inform him of this requirement, and that the defendants then reported to the FAA that the plaintiff had refused to test, which caused the plaintiff adverse professional consequences. See id. at 822. The court held that on these facts, the defendants did not owe the plaintiff a duty of care arising from the DOT's "ministerial" notice requirement, and clarified that Landon stood for the proposition that a drug-testing laboratory or drug-testing program administrator's duty of care arose from its "failure to adhere to professionally accepted scientific testing standards in the testing of the biological sample." Id. at 826. Stated differently, Pasternack held a drug-testing laboratory or drug-testing program administrator's duty of care under New York negligence law is created by a failure to adhere to standards that "implicate the scientific integrity of the testing process[.]" Id. at 826-27.

In response to Plaintiff's argument that Defendants owed her a duty akin to the one found in Landon, Defendants rely on Pasternack for support for their proposition that no such duty is owed because they are not a drug-testing laboratory just like the one in Landon. See ECF No.

48-1 at 11. To the contrary, the New York Court of Appeals stated in Pasternack that both drug testing laboratories and drug-testing "program administrators" could owe a duty to their subjects, Pasternack, 27 N.Y.3d at 826-27 (emphasis added).[8] Defendants also argue that Plaintiff has not alleged that they were "in the best position to prevent false positive tests," which Landon found pertinent to the laboratory's duty. See ECF No. 48-1 at 12; Landon, 22 N.Y.3d at 6. Yet, Plaintiff does plausibly allege that Defendants were in the best position to prevent false positive results given that DOCCS's inmate urinalysis testing relied upon Defendants' warranties that their IPUA machines, products and service platforms would be provided consistent with relevant professional standards. See FAC ¶¶ 22, 26-29, 40, 45; Sections I.c-g, supra. Among other things, allegations regarding Defendants' training and tester proficiency certification services show the significant authority Defendants were given over the program due to their knowledge and expertise vis-à-vis IPUA urine scans and the system's proper operation. See Exh. 1 at 81; Sections I.c-g, supra. At several stages of the process, Defendants could have notified DOCCS about or taken steps to correct the erroneous testing process. See Gonzalez v. Aramark Food & Support Servs. Grp., Inc., No. 09 Civ. 4843 (CBA), 2012 WL 1019982, at *7 (E.D.N.Y. Mar. 26, 2012) (finding that the breadth of defendant food service contractor's training and management responsibilities meant it was "[c]ertainly in the best position to prevent hazards" arising from food service equipment that had harmed a third-party negligence claimant).

Further, the boundaries of duty may also take into account the parties' "contractual

[8] Defendants' argument that they cannot be said to have had a duty because they are not a drug-testing laboratory also incorrectly relies upon New York Public Health Law § 271(1)'s definition of a "clinical laboratory." See ECF No. 48-1 at 12. That law's definition of "clinical laboratory" does not apply to "any facility or activity" pertaining to examinations performed by state or local agencies of materials derived from the body of an inmate to determine the presence or absence of any substance prohibited by DOCCS. See N.Y. Pub. Health L. § 271(1)); N.Y. Pub. Health L. § 579(2).

assumptions of responsibility." Braverman v. Bendiner & Schlesinger, Inc., 121 A.D.3d 353, 361 (2d Dep't 2014) (quoting Palka, 83 N.Y.2d at 585). As relevant here, this is because where contracting parties reasonably perceive risk to third parties in a contract's performance and themselves identify which of them is in the best position to avoid causing that potential harm, it is fair to say that the risk they perceived "defines the duty to be obeyed[.]" Id. (quoting Palsgraf v. Long Is. R.R. Co., 248 N.Y. 339, 344 (N.Y. 1928)). Here, Defendant Microgenics not only warranted that Defendants would provide an extensive platform of IPUA products and services consistent with certain standards for inmate urinalysis testing at DOCCS, it also agreed to hold the People of New York and DOCCS harmless with respect to liabilities—including negligence claim liability—arising from the performance of those obligations. See Exh. 1 at 17 § XVI.g; Section I.e, supra. Although this factor is not dispositive, it is a factor suggesting Defendants owed a duty of care to Plaintiff. See Palka, 83 N.Y.2d at 582 (finding that defendant corporation owed plaintiff nurse a duty of care in connection with the defendant's premises-maintenance management and training contract with her hospital employer after an uninspected fan fell and injured the plaintiff after noting, among other things, the "particularity of [the defendant's] assumed responsibility under the contract" in agreeing to hold the hospital harmless for any liability arising from the defendant's acts and omissions thereunder); see also Gonzalez, 2012 WL 1019982, at *6 (noting that "[i]n essence, Palka recognizes a duty when, as a result of a contract, one party fully assumes the other's responsibilities in a specific, articulable sphere to a reasonably predictable, identifiable class of individuals").

Next, the Court finds unavailing Defendants' argument that Braverman requires the dismissal of Plaintiff's complaint for not "plausibly alleg[ing] a relevant professional standard" which Defendants failed to follow. See ECF No. 48-1 at 12-13; Braverman, 121 A.D.3d at 359.

This case is distinguishable from Braverman in which the plaintiffs did not allege false positives, acknowledged the validity of testing procedures, admitted that the clinical testing was properly performed, and agreed "no professional standards [were] implicated" by the plaintiffs' allegation that the defendants should have put a "for clinical purposes only" disclaimer on drug test reports. Id. at 358-60. In contrast, Plaintiff here alleges that Defendants had warranted that their IPUA systems would be "substantially uninterrupted or error-free in operation" by conforming to Defendants' own "specifications, performance standards, and documentation[,]" and that Defendants' failure to adhere to those specifications and standards—even in the face of an atypically high rate of false positive complaints—unreasonably gave rise to cross-reactivity problems that compromised the accuracy and scientific integrity of the urine scans. See FAC ¶ 30; Sections I.c-g, supra; cf. Stinnert v. Delta Air Lines, Inc., No. 18 Civ. 2704 (DLI) (LB), 2019 WL 1493224, at *11 (E.D.N.Y. Mar. 31, 2019) (finding that plaintiff had not pleaded that the defendant laboratory failed to use professionally accepted scientific methodology as Pasternack required). The Court finds unconvincing Defendants' argument that Plaintiff has not identified which of Defendants' internal specifications and standards Defendants failed to follow. Plaintiff alleges that Defendants were required "to abide by applicable drug testing standards . . . to ensure that the testing was accurate and reliable[,]" See FAC ¶ 33, and examples of such standards bearing on the IPUA system's scientific integrity are contained in the very motion exhibits that Defendants themselves urge the Court to consider as part of Plaintiff's FAC or as judicially noticeable records, including: (i) SAMHSA detection cutoff levels that Defendants warranted the IPUA system would meet or exceed; (ii) the CLSI standards and guidelines that the FDA referenced as applicable to Defendants' buprenorphine assays and Defendants' warranty that their reagents were FDA-approved; and (iii) the DOCCS's Statement of Scientific Principles and

Validity of Testing Apparatus about IPUA urinalysis that made representations about the reliability and accuracy of IPUA systems when operating properly, see Section I.a, supra; Sections I.d-f, supra; Exh. 1 at 117, 119 (bid and Contract stating that IPUA's measurements would meet or exceed SAMHSA cutoff detection guidelines); Exh. 4 at 4 at 189-192 (stating critical parameters guiding IPUA's proper operation); Exh. 5 (FDA record referencing CLSI guidelines and standard); Exh. 6 (same); Landon, 22 N.Y.3d at 4-5 (finding that the defendant's duty arose from its alleged failure to adhere to SAMHSA's recommended cutoff levels by using a significantly lower cutoff). Plaintiff is not required to plead these standards at a greater level of specificity than what she has done.

The Court notes that Defendants also argue that they did not owe Plaintiff a duty, as Plaintiff alleges, to disclose to DOCCS that confirmatory tests should be performed upon positive IPUA results because DOCCS was already aware of the benefits of such confirmatory testing for urine scans (it required it when drug testing parolees and employees) but elected not to make it a part of its inmate urinalysis program. See ECF No. 48-1 at 14-15; compare Exh. 2 (DOCCS Directive 9432 regarding parolee drug testing) and Exh. 3 (DOCCS Directive 2115 regarding employee drug testing) with Exh. 4 (DOCCS Directive 4937 regarding inmate urinalysis program). In effect, Defendants argue that this is a description of a standard but not one that applied here because DOCCS's IFB sought only inmate urinalysis testing products and services such that Defendants were not required to question DOCCS's informed election or provide confirmatory testing that the Contract did not entail. See ECF No. 48-1 at 14-15; Exh. 1 at 80-82. The Court disagrees. Even if one were to accept that DOCCS had historically used urinalysis systems that it understood to require confirmatory tests to verify, Plaintiff's claim that Defendants promised DOCCS that their IPUA system would be "substantially uninterrupted or error-free in operation"

plausibly alleges that during the bid process and contract negotiation with DOCCS, Defendants warrantied a uniquely accurate urinalysis system. FAC ¶ 30; see, e.g., Exh. 4 at 189 (Statement of Scientific Principles and Validity of the Testing Apparatus stating without mention of cross-reactivity that the urinalysis tests "were designed as a primary screening system" and that although the system's reagents "are not designed to measure the quantity of drug in a sample, [they] will distinguish a positive from a negative sample") (emphases added); id. at 190 (describing the percentages of accurate positive urinalysis screens as comparable and arguably better to those obtained with gas chromatography or thin-layer chromatography); id. (noting that analyzing 100 urine samples using a marijuana assay "did not give a single false positive result"); id. (noting reliability of reagents on the IPUA machine). If so, then there is a reasonable possibility of a fact issue regarding whether Defendants were negligent in failing to disclose to DOCCS that however near to error-free their IPUA system operated, it still required the same confirmatory testing as other urinalysis screens to verify reliability.

The Court notes that although a court in this Circuit recently dismissed a pro se plaintiff's negligence action against these same Defendants arising from the same events for failure to state a claim, that case is distinguishable from the instant case. See Velez v. Microgenics Corp. ("Velez I"), No. 20 Civ. 387 (JLS), 2020 WL 4043240, at *1 (W.D.N.Y. July 16, 2020); Velez v. Microgenics Corp. ("Velez II"), No. 20 Civ. 387 (JLS), 2021 WL 730232, at *3 (W.D.N.Y. Feb. 23, 2021). In Velez I, the court held that the pro se plaintiff's original complaint impermissibly rested on unspecified, conclusory and speculative allegations and granted him leave to cure the defects with an amended complaint with additional factual allegations addressing the original's deficiencies. See Velez I, 2020 WL 4043240, at *3. Instead, the pro se plaintiff filed an amended complaint that restated the same factual allegations in his original pleading; finding that the

plaintiff had squandered the invitation to cure pleading defects in his amended complaint, the court dismissed it. See Velez II, 2021 WL 730232, at *3-4. In summary, Plaintiff's plausible allegations here with the assistance of counsel are a far cry from the pro se plaintiff's misunderstanding of his pleading burden in Velez I and Velez II.

In light of the foregoing, the Court finds that Plaintiff has sufficiently alleged that Defendants owed Plaintiff a duty of care. See Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC, 797 F.3d 160, 178 (2d Cir. 2015) (finding that plaintiffs can survive a Rule 12(b)(6) motion to dismiss where an inference from their pleading is "cogent and at least as compelling" as the contrary one, and that whether plaintiff "can ultimately prove their account" is different question).

c. Plaintiff Plausibly Alleged That Defendants Breached Their Duty Of Care

Under New York law, in a negligence action, once the court has determined the existence of a duty of care, "it is then the factfinder's job to determine whether the duty was breached and, if so, whether the breach was the proximate cause of [the] plaintiff's injury." Gonzalez v. Caballero, 572 F. Supp. 2d 463, 467 (S.D.N.Y. 2008) (citing Palka, 83 N.Y.2d at 585, and Lombard v. Booz-Allen & Hamilton, Inc., 280 F.3d 209, 215-16 (2d Cir. 2002)); see Guzman v. Wackenhut Corp., 394 F. App'x 801, 803 (2d Cir. Oct. 1, 2010) (noting that although the existence of a duty of care is usually a question of law, "[i]t is for the fact-finder to determine whether the duty was breached and, if so, whether the breach was the proximate cause of [the] plaintiff's injury") (citation omitted); Cates v. Trs. of Columbia Univ., No. 16 Civ. 6524 (GBD) (SDA), 2019 WL 8955333, at *11 (S.D.N.Y. Oct. 25, 2019) ("If a factfinder concludes that [the defendant's] conduct amount to a breach of duty under the circumstances, this evidence is sufficient for the factfinder to conclude that the alleged breach caused [the plaintiffs']

damages."). Here, Plaintiff plausibly alleges a breach of the duty of care in that Defendants' provision of their IPUA system and services failed to adhere to the standards discussed, supra, in Section III.b, and, as a consequence, the compromised accuracy and scientific integrity of positive IPUA urine scans gave rise to her false positive drug report and related damages described, supra, in Sections I.g-h. See Landon, 22 N.Y.3d at 4-5 (finding the plaintiff to have sufficiently alleged the defendant's breach of a duty by failing to perform drug test on the plaintiff's biological sample in keeping with multiple industry and governmental standards); see, e.g., supra, Section I.i (discussing DOCCS's reversal of all disciplinary decisions based on positive IPUA screens and cancelled the Contract after determining that IPUA system cross-reactivity problems compromised its warranted reliability).

In light of the foregoing, the Court finds that Plaintiff has sufficiently alleged that Defendants breached their duty of care. See Loreley Fin. (Jersey) No. 3 Ltd., 797 F.3d at 178.

d. Plaintiff Plausibly Alleged Defendant Thermo Fisher's Liability

A parent corporation can be held liable for the torts of a partially owned subsidiary with evidence showing the parent exercised sufficient domination and control over its subsidiary. See Lener v. Club Med, Inc., 168 A.D.2d 433, 435 (2d Dep't 1990) (finding that plaintiff failed to present a fact issue regarding whether parent corporation exercised such complete domination and control over subsidiary that it could be held liable for the subsidiary's torts). "The control must actually be used to commit a wrong against the plaintiff and must be the proximate cause of the plaintiff's loss." Musman v. Modern Deb, Inc., 50 A.D.2d 761, 762 (1st Dep't 1975) (citation omitted). Applying these standards, the Court finds unconvincing Defendant Thermo Fisher's argument that Plaintiff has not plausibly alleged its liability in this action because Defendant Microgenics was the nominal Contractor to the DOCCS Contract. See ECF No. 47-

1; Exh. 1 at 3-158; Exh. 5; Exh. 6. The duty to avoid harm to others, which Plaintiff has plausibly alleged here, see Section III.b, supra, is distinct from the contractual duty of performance[,]" Landon, 22 N.Y.3d at 6; see Bayerische Landesbank, N.Y. Branch v. Aladdin Cap. Mgmt., LLC, 692 F.3d 42, 58 (2d Cir. 2012) (A duty of care "spring[s] from circumstances extraneous to, and not constituting elements of, [a] contract.") (citation & internal quotation marks omitted). Accordingly, at this juncture, Plaintiff's allegations that Defendants jointly committed breached a duty of care in their provision of IPUA system and services pursuant to the Contract—as distinguished from a contract breach—are sufficient to plausibly plead Defendant Thermo Fisher's liability. See Sections I.d-e, g-h, supra; Wynder v. McMahon, 360 F.3d 73, 80 (2d Cir. 2004) (finding that Rule 8 does not "necessarily require . . . that the complaint separate out claims against individual defendants"); Sabol v. Bayer Healthcare Pharm., Inc., 439 F. Supp. 3d 131, 145-46 n.11 (S.D.N.Y. 2020) (rejecting that the plaintiff failed to state a claim where pleading did not differentiate between two corporate entities, and alleging the corporate parent's "manufacturing, testing, licensing, design, marketing, selling, distributing, and advertising" of the product); A.B. v. ICC Indus., Inc., No. 91 Civ. 1748 (MBM), 1991 WL 161367, at *1 (S.D.N.Y. Aug. 16, 1991) (denying defendants' motion to dismiss them as improper parties to suit and permitting plaintiff to develop facts to prove theory of liability against parent corporation); A.W. Fiur Co. v. Ataka & Co., 71 A.D.2d 370, 373-74 (1st Dep't 1979) (finding that evidence "at least raise[d] a question whether [the parent corporation] so controlled the actions of [its subsidiary] that unitary liability to the plaintiff arising from the actions of the defendants could be imposed on both corporations"). For the same reasons, Defendant Thermo Fisher's argument that it did not breach terms of the Contract fails; "[a] person is not necessarily insulated from liability in tort merely because he or she is engaged in

performing a contractual obligation." Banco Multiple Santa Cruz, S.A., v. Moreno, 888 F. Supp. 2d 356, 367 (E.D.N.Y. 2012) (quoting Landon v. Kroll Laboratory Specialists, Inc., 91 A.D.3d 79, 83 (2d Dep't 2011)).

Defendant Thermo Fisher also makes the unpersuasive argument that it cannot have owed a duty to Plaintiff because it was not the nominal applicant for the FDA's clearance for the IPUA machine or buprenorphine assays.[9] This fact does little to distance Defendant Thermo Fisher from Plaintiff's plausible allegations that Defendants jointly failed to adhere to relevant standards when providing IPUA systems and services, see FAC ¶¶ 9-10, 25; Exh. 1 at 114-158; Sections I.a, d-e, supra; Lener, 168 A.D.2d at 435; Musman, 50 A.D.2d at 762, or Plaintiff's plausible allegations that Defendant Thermo Fisher was so invoked and involved in the IFB bidding and contract negotiation processes it should be treated a party to the Contract with Defendant Microgenics, see Sections I.d-e, supra; Warnaco, Inc. v. VF Corp., 844 F. Supp. 940, 946 (S.D.N.Y. 1994) (noting that a parent corporation may be found to be a party to its subsidiary's agreement if the parent's conduct manifests an intent to be bound); A.W. Fiur Co., 71 A.D.2d at 373 (noting that a parent corporation may be found to be a party to its subsidiary's contract if the parent had a role in negotiating the agreement and intended for its subsidiary to be a dummy for the parent).

In light of the foregoing, the Court finds that Plaintiff's allegations plausibly support Defendant Thermo Fisher is a proper Defendant in the action.

[9] Although Plaintiff objects to the Court's consideration of the content of these FDA records for the limited purposes for which Defendants invoke them in connection with the argument that Defendant Thermo Fisher should be dismissed from the action, insofar as the Court does not find them controlling and declines to dismiss Defendant Thermo Fisher, it does not reach whether Defendants permissibly rely on the FDA information. See ECF No. 47-4 at 5 n.3.

IV. Defendants' Rule 12(f) Motion To Strike Plaintiff's Class Allegations

Motions to strike are governed by Rule 12(f) which provides, in pertinent part, that a court "may strike from a pleading . . . any redundant, immaterial, impertinent, or scandalous matter" upon motion. Fed. R. Civ. P. 12(f). "Motions to strike are generally disfavored, and should be granted only when there is a strong reason for doing so." Mazzola v. Roomster Corp., 849 F. Supp. 2d 395, 410 (S.D.N.Y. 2012) (citation & internal quotations omitted); see Reynold v. Lifewatch, Inc., 136 F. Supp. 3d 503 (S.D.N.Y. 2015) ("Motions to strike under Rule 12(f) are rarely successful."); Belfiore v. Procter & Gamble Co., 94 F. Supp. 3d 440, 447 (E.D.N.Y. 2015) ("Courts rarely grant motions to strike pursuant to [Rule] 12(f)."). "Moreover, a motion to strike class allegations . . . is even more disfavored because it requires a reviewing court to preemptively terminate the class aspects of . . . litigation, solely on the basis of what is alleged in the complaint, and before plaintiffs are permitted to complete the discovery to which they would otherwise be entitled on questions relevant to class certification." Mazzola, 849 F. Supp. 2d at 410 (citations & internal quotations omitted); see Kronenberg v. Allstate Ins. Corp., No. 18 Civ. 6899 (NGG) (JO), 2020 WL 1234603, at *6 (E.D.N.Y. Mar. 13, 2020) (denying the defendants' motion to strike the plaintiff's class allegations, finding the defendants could not "demonstrate from the face of the [c]omplaint that it would be impossible to certify the alleged class regardless of facts [the p]laintiffs may be able to obtain during discovery") (quoting Mayfield v. Asta Funding, Inc., 95 F. Supp. 3d 685, 696 (S.D.N.Y. 2015). Accordingly, courts in the Second Circuit "have frequently found that a determination of whether the Rule 23 requirements are met is more properly deferred to the class certification stage, when a more complete factual record can aid the [c]ourt in making this determination." Mazzola, 849 F. Supp. 2d at 410 (collecting cases).

Applying these standards, this Court declines to dismiss Plaintiff's class allegations at this juncture. Defendants argue that Plaintiff's definition of her class as all inmates whose disciplinary decisions were reversed by DOCCS is over-inclusive because some of those inmates' positive IPUA scans may have been accurate. See ECF No. 48-1 at 19-25. Although this flags a dispute that the parties may need to litigate at the class certification stage, courts faced with similar pleading-stage class standing arguments have found that this is not a basis for denying class discovery. See Med. Soc'y of New York v. UnitedHealth Grp. Inc., No. 16 Civ. 5265 (JPO), 2018 WL 1773142, at *2 (S.D.N.Y. Apr. 12, 2018) ("[D]iscovery will shed light on . . . the likely difficulty (or ease) of excluding individuals who lack standing to sue."); Petrosino v. Stearn's Prod., Inc., No. 16 Civ. 7735 (NSR), 2018 WL 1614349, at *5 (S.D.N.Y. Mar. 30, 2018) (deferring consideration of class standing questions to the class certification stage and collecting cases). Defendants also unavailingly argue that the Court should strike Plaintiff's class allegations because they will potentially require the Court to make individualized inquiries into proximate causation, for example, if IPUA's cross-reactivity problems principally affected scans for one drug of abuse but not others. See ECF No. 48-1 at 19-25. Yet, if discovery corroborates Plaintiff's allegation that more general IPUA machine, product or service failures caused false scan positives for putative class members, there is a possibility that common questions of fact will emerge that predominate over individualized ones. See Fed. R. Civ. P. 23(b)(3); Haley v. Tchrs. Ins. & Annuity Ass'n of Am., 377 F. Supp. 3d 250, 273 (S.D.N.Y. 2019) (denying motion to strike class allegations cast as pleading challenge "separate" from those raised during class certification stage, finding that "[s]uch arguments implicate typicality and whether common questions predominate for the class, and thus rely upon the [Rule 23] factors that would be analyzed and addressed . . . in the course of deciding a motion for class.")

(quoting Campbell v. Chadbourne & Park LLP, No. 16 Civ. 6832 (JPO), 2017 WL 2589389, at *4 (S.D.N.Y. June 14, 2017); Farina v. Metro. Transp. Auth., 409 F. Supp. 3d 173, 220 (S.D.N.Y. 2019) ("Whether a plaintiff can satisfy the requirements of Rule 23 are more properly decided on a class certification motion."); Carrillo v. Wells Fargo Bank, N.A., No. 18 Civ. 3095 (SJF) (SIL), 2019 WL 3714801, at *12 (May 10, 2019), report & recommendation adopted, 2019 WL 3927369 (E.D.N.Y. Aug. 20, 2019) ("A plaintiff need not . . . prove [Rule 23(b)(3)] factors prior to discovery."); Med. Soc'y of N.Y., 2018 WL 1773142, at *2.

V. Conclusion

For the foregoing reasons, the Court denies Defendants' motions to dismiss pursuant to Rule 12(b)(6) and motion to strike Plaintiff's class allegations pursuant to Rule 12(f). See ECF Nos. 47-48.

Dated: Brooklyn, New York
March 22, 2021

Vera M. Scanlon
VERA M. SCANLON
United States Magistrate Judge