Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2266032	06/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Microwell Laboratories Inc	13770 58th St N Ste 315, Clearwater, FL	

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
D0000	An announced initial survey was conducted on 06/15/2023 to 06/20/2023 at Microwell Laboratories Inc, a clinical laboratory in Clearwater, FL. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Clinical Laboratories. Based on survey findings, an Immediate Jeopardy situation was identified, and the laboratory was notified at 3:25 PM on 06/20/2023. The following Condition was not met: D5400 - Analytic Systems 493.1250
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the test menu, policy and procedure manual, the food allergen log, and interview, the laboratory failed to use a positive control with graded reactivity for the laboratory developed test, IgG (Immunoglobulin G) Pinnertest/IG assay, which tests for 200 food proteins on the GeneMachine and Innopsys scanner each day of patient testing. The laboratory tested and reported 1,635 patients from 09/09/2022 to 06/08/2023 (See D5451).
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--

	At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the test menu, policy and procedure manual, the food allergen log, and interview, the laboratory failed to use a positive control with graded reactivity for the IgG (Immunoglobulin G) Pinnertest/IG assay, which tests for 200 food proteins on the GeneMachine and Innopsys scanner each day of Patient testing. The laboratory tested and reported 1,635 patients from 09/09/2022 to 06/08/2023. Findings included: Review of the test menu provided with Clinical Laboratory Improvement Amendment (CLIA) Application for Certification indicated the following 200 food proteins were tested using the GeneMachine and Innopsys scanner: agar, agave, allspice, almond, aloe vera, amaranth, anchovy, anise seeds. apple, apricot, artichoke, asparagus, roquette, goat, avocado, lemon grass, banana, barley, basil, beef, beet, bell pepper, black bean, black tea, blackberry, blueberry, vine leaf, Brazil nut, broccoli, Brussels sprouts, buckwheat, butternut squash, cabbage, cane sugar, rapeseed, cantaloupe, capers, cardamom, carob, carrot., cashew nut, cauliflower, celery, chamomile tea, chard, cherry, chestnut, chicken, chickpea, chicory, chili pepper, chives, coriander, cinnamon, clam, clove, cacao, coconut, codfish, coffee, cola nut, lime blossom tea, corn, cow's milk, crab, cranberry, cucumber, cumin, black currant, date, dill, duck meat, eel, egg white, egg yolk, eggplant, coconut milk, broad bean, fennel, fig, flax seed, fructose, garlic, ginger, ginseng, gluten, goat's milk, grape, tamarind, grapefruit, guava, haddock, hazelnut, cannabis, green tea, hibiscus, honey, hops, soy milk, kale, kamut wheat, kidney beans, kiwi, lamb, lavender, leek, lemon, lentils, lettuce, lime, lobster, macadamia nut, mackerel, mango, maple syrup, millet, peppermint, mushroom, mussel, mustard seeds, nectarine, nutmeg, oat, octopus, okra, black olive, onion, orange, oregano, oyster, papaya, paprika, parsley, pea, peach, peanut, pear, pectin, black pepper, pine nut, pineapple, white beans, pistachio, plum, pomegranates, poppy seeds, pork, potato, pumpkin, quail, quinoa, rabbit, radicchio, horseradish, black-eyed pea, rhubarb, rice, rooibos, rosemary, swede, rye, durum wheat, saffron, sage, salmon, sardine, scallop, sea bass, sesame seeds, sheep's milk, shrimp, sole, soybeans, spelt, spinach, squid, strawberry, green bean, mandarine, sunflower seeds, sweet potato, swordfish, tapioca, tarragon, thyme, tilapia, tomato, rainbow trout, yellowfin tuna, turkey, turmeric, turnip, vanilla, walnut, water cress, watermelon, wheat, baker's yeast, brewer's yeast, and zucchini. Review of the procedure manual signed by the Laboratory Director (LD) on 09/01/2022 revealed to "Pipette 200 ul of processed dry blood component (DBC) into the appropriate slide wells except for the well position 9, which is used for buffer control" The buffer control is what the laboratory considered to be the negative control. Patient results are reported out "using the +3, +2, +1 degree nomenclature" which would require a positive control with graded activity to be ran each day of patient testing. Review of the Food Proteins log revealed 1,635 patient specimens were tested with a negative control and reported without a positive control with graded activity from 09/09/22 - 06/08/2023. On 06/15 /2023 at 1:30 PM, the Owner confirmed a positive control was not used when performing the allergen testing. On 06/20/2023 at 3:29 PM, the Laboratory Director confirmed a positive control was not used when performing the allergen testing.