

CANADA

PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

No.: 500-06-001214-226

(Class Action)
SUPERIOR COURT

RACHEL DRESDEN, 


Applicant

v.

ORTHO CLINICAL DIAGNOSTICS, legal person duly constituted, having its principal place of business at Felindre Meadows, Bridgend, Great Britain, CF35 5PZ.

and

ORTHO CLINICAL DIAGNOSTICS INC., legal person duly constituted, having its principal place of business at 1001 Route 202, Raritan, New Jersey, 08869.

and

ORTHO-CLINICAL DIAGNOSTICS CANADA HOLDINGS CORPORATION, legal person duly constituted, having its principal place of business at 4529 Melrose Street, Port Alberni, British Columbia, V9Y1K7.

and

OPTILAB MONTRÉAL-MUHC, located at 1001, boulevard Décarie, bureau E04.1642, in the City of Montreal, Province of Québec, H4A 3J1.

and

SAINT-MARY'S HOSPITAL, located at 3830 Av. Lacombe, in the City of Montreal, Province of Québec, H3T 1M5.

and

LAKESHORE GENERAL HOSPITAL, located at 160 Stillview Avenue, in the City and District of Pointe-Claire, Province of Québec, H9R 2Y2.

and

HÔPITAL DE LASALLE, located at 8585 Terrasse Champlain, in the City and District of LaSalle, Province of Québec, H8P 1C1.

and

PROCEREUR GÉNÉRAL DU QUÉBEC, acting as representative for the Ministère de la Santé et des Services sociaux, having his place of business at 1 rue Notre Dame Est, bureau 800, in the city of Montréal, Province of Québec, H2Y 1B6.

Solidary Defendants

**AMENDED APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION
AND TO
APPOINT THE STATUS OF REPRESENTATIVE PLAINTIFF
(Articles 571 C.C.P. and following)**

TO ONE OF THE HONOURABLE JUSTICES OF THE QUÉBEC SUPERIOR COURT, SITTING IN AND FOR THE DISTRICT OF MONTRÉAL, THE APPLICANT STATES AS FOLLOWS:

1. **INTRODUCTION**

- 1.1 The human immunodeficiency virus (HIV) targets the health immune system and weakens people's ability to fight off infections. Infected individuals gradually become immunodeficient;

- 1.2 HIV can be transmitted through body fluids from infected people, such as blood, breast milk, semen and vaginal secretions. It can also be transmitted from a mother to her child during pregnancy and delivery;
- 1.3 Rapid diagnosis of HIV is primordial in preventing the spread and transmission of the disease;
- 1.4 With antiretroviral (ARV) drugs, the disease can be managed;
- 1.5 Tragically, individuals who underwent HIV testing at the Saint-Mary's Hospital, the Lakeshore General Hospital or the Lasalle Hospital between December 2021 and September 2022 with recalled lots of reagents provided by Ortho Clinical Diagnostics and/or OPTILAB Montréal-CUSM were at risk of an incorrect result;
- 1.6 The recalled lot of reagents, manufactured by Defendant Ortho Clinical Diagnostics have generated false negative results when testing HIV samples;
- 1.7 As of August 30, 2022, there was a Health Product Recall on the affected lot of reagents (see Health Product Recall attached herein as **Exhibit P-1**);
- 1.8 Due to the risk of incorrect results, all affected patients have been, or are being advised to contact their doctors or nurse to reschedule their lab test, as per the letter dated November 29, 2022 sent by Defendant OPTILAB Montréal MUHC to the Applicant (attached herein as **Exhibit P-2**);
 - 1.8a) On December 29, 2022, CTV News aired a report entitled "HIV tests used at Montreal hospitals recalled after suspect results noticed". A copy of the written article published by CTV News is produced herein as **Exhibit P-3**;
 - 1.8b) According to the report by CTV News, "The McGill University Health Centre (MUHC) has identified approximately 9,000 patients who may have received false negatives through recalled HIV tests";
 - 1.8c) Following the recall, the MUHC notified Québec's Health Ministry; significantly, neither organization publicly announced the news;
 - 1.8d) The Québec Ministry of Health confirmed to CTV News that some of the samples yielded false negatives;
- 1.9 The present class action seeks redress and compensation for the events described below:

2. THE PARTIES

- 2.1 The Applicant is an individual who underwent HIV testing at the Defendant Saint-Mary's Hospital on January 20, 2022;
- 2.2 Defendant Ortho Clinical Diagnostics is a global provider of solutions for screening, diagnosing, monitoring and confirming diseases; they advertise that their VITROS HIV Combo tests as "designed to inspire confidence in the results your laboratory provides" (See Ortho Clinical Diagnostics flyer for VITROS Immunodiagnostic Products HIV Combo Reagent Pack and Calibrator attached herein as **Exhibit P-4**);
- 2.3 Optilab Montréal-MUHC is a multisite laboratory comprised of the 12 Optilab clusters in Quebec;
- 2.4 The Defendants, Saint-Mary's Hospital, the Lakeshore General Hospital and the Lasalle Hospital are accredited hospitals properly staffed and equipped to preform laboratory tests, including HIV testing;
- 2.5 The Ministère de la Santé et des Services sociaux (MSSS) is responsible for the administration of health and social services in the Province of Québec;

3. THE APPLICANT WISHES TO INSTITUTE A CLASS ACTION ON BEHALF OF THE CLASS OF PERSONS HEREINAFTER DESCRIBED:

- A. All individuals who underwent laboratory tests at the Saint-Mary's Hospital, the Lakeshore General Hospital or the Lasalle Hospital between December 2021 and September 2022 which were done with recalled lots of reagents provided by Ortho Clinical Diagnostics and/or OPTILAB Montréal-CUSM and who sustained damages, as a result of the negligence of the Defendants.
- B. All individuals who underwent said laboratory tests who were in fact HIV positive but received negative results.
- C. All individuals who contracted HIV or were placed at risk of contracting HIV as a result of the false negative results provided to individuals in subparagraphs A and B.
- D. The spouses and children of individuals in subparagraphs A, B and C.

4. THE APPLICANT'S PERSONAL CLAIM AGAINST THE DEFENDANTS IS BASED ON THE FOLLOWING FACTS:

- 4.1 On January 20, 2022, the Applicant, Rachel Dresden, underwent a blood test for HIV at the Defendant Saint-Mary's Hospital;

- 4.2 Her test results were available on January 20, 2022 and they revealed a negative result (see Serology results dated January 20, 2022 attached herein as **Exhibit P-5**);
- 4.3 Eleven months later, on December 13, 2022, the Applicant received a letter in the mail, dated November 29, 2022, from Defendant Optilab Montréal-MUHC informing her that there was a risk the laboratory tests she had undergone had an inaccurate result (see **Exhibit P-2**);
- 4.4 Immediately upon reading this letter, the Applicant telephoned the helpline indicated in the letter to receive further information;
- 4.5 The Applicant was required to leave a message with her name and RAMQ number; when she was called back by a Defendant Optilab Montréal-MUHC nurse, very little information was disclosed other than that all individuals who underwent HIV testing at the Defendant Hospitals during the Class period could have received inaccurate results and that they were arranging to have secondary blood tests arranged for the over 9,000 people who were affected;
- 4.6 Safety and health were important concerns for the Applicant, who was reassured by the negative HIV results from her January 2022 blood test; consequently, from January 2022 to December 13, 2022, she had conducted her life as if she was HIV negative;
- 4.7 The Applicant quickly made arrangements to be re-tested for HIV on December 13, 2022;
- 4.8 On December 16, 2022 the Applicant was informed that the December 13, 2022 HIV test result was negative;

5. **NEGLIGENCE OF THE DEFENDANTS**

Product Defects:

- 5.1 As manufactures, distributors, suppliers, wholesalers and/or importers of the recalled reagent lot, Defendant Ortho Clinical Diagnostics are bound to warrant Class members that their HIV tests were free from defects which risk rendering incorrect results;
- 5.2 Defendant Ortho Clinical Diagnostics failed and neglected to ensure quality control procedures by manufacturing and distributing HIV reagents generating false negative results;

Defendants' failure to disclose the affected lot of reagents in a timely manner

- 5.3 The Defendants acted with gross negligence in failing and neglecting to immediately inform the affected patients that there was a risk that their HIV test results were inaccurate;
- 5.3a) The Defendants acted with gross negligence in failing and neglecting to immediately inform the general public of the recall, given that this constituted a serious public health concern not only for the affected patients, but their families and third party contacts as well;
- 5.4 The Applicant was only informed of the risk of an inaccurate result 11 months after her HIV test;
- 5.5 Moreover, in the letter she received from Optilab Montréal-MUHC, there was no disclosure of what had occurred, nor which test was at risk of an incorrect result;
- 5.6 Upon calling the help line indicated in the letter, the Applicant was required to leave a message with her name and RAMQ number; when she was called back by a nurse, very little information was disclosed;
- 5.7 The obligation to immediately inform the affected patients was even more important in the circumstances given the serious nature of the disease and implications of HIV transmission;
- 5.8 The Defendants knew or ought to have known that the start date of the recall was August 30, 2022 and that Health Canada had published the product recall on September 14, 2022;
- 5.8a) Moreover, following the recall, the MUHC and Defendant Optilab Montréal-MUHC notified Québec's Health Ministry of the recall however neither organization publicly announced the news;
- 5.8b) Instead of immediately informing patients and the general public, Defendant Optilab Montréal-MUHC sent letters to patients' doctors;
- 5.9 Instead of immediately informing patients and the general public, the Defendants used their resources to set up dedicated blood stations at the Defendant Saint-Mary's Hospital and Lakeshore General Hospital for the affected patients to be re-tested once they were informed of the recall;

- 5.10 The Defendants knew or ought to have known that the failure to disclose the affected lot of reagents in a timely manner would have devastating consequences for the Class members;

6. DAMAGES

- 6.1 In light of the foregoing, the following damages may be claimed solidarily against the Defendants:

- a) Compensatory damages, in an amount to be determined, on account of the damages suffered; and
- b) Punitive damages, in an amount to be determined, for the breach of section 49 of the Charter:
 - i. Punitive damages have a preventive objective, that is, to discourage the repetition of such undesirable conduct;
 - ii. The Defendants knew of the risk of incorrect results related to this recalled lot of reagents as early as August 30, 2022, yet failed and neglected to immediately inform the affected individuals and the general public of the recall, given that this constituted a serious public health concern not only for the affected patients, but their families and third party contacts as well;
 - iii. The Defendants' violations were intentional, [...] grossly negligent and dangerous;
 - iv. Through its behavior, the Defendants demonstrate that it was more concerned with protecting themselves than about ensuring the safety and health of Class members;
 - v. In these circumstances, Applicant's claim for punitive damages is justified;

7. THE PERSONAL CLAIMS OF EACH OF THE MEMBERS OF THE CLASS AGAINST THE DEFENDANTS ARE BASED ON THE FOLLOWING FACTS:

- 7.1 All individuals [...] have been affected by the laboratory tests performed at the Saint-Mary's Hospital, the Lakeshore General Hospital or the Lasalle Hospital between December 2021 and September 2022 which were done with recalled lots of reagents provided by Ortho Clinical Diagnostics and/or OPTILAB Montréal-CUSM;

- 7.2 None of the members of the class were notified sufficiently and in a timely manner by the Defendants of the risk of false negative results;
- 7.3 Each member of the class shall be entitled to make a claim for damages for bodily, moral and/or material injuries suffered, as a result of the recalled lot of reagents, as well as for punitive damages, if applicable;

8. **THE COMPOSITION OF THE CLASS MAKES IT DIFFICULT OR IMPRACTICABLE TO APPLY THE RULES FOR MANDATES TO TAKE PART IN JUDICIAL PROCEEDINGS ON BEHALF OF OTHERS OR FOR CONSOLIDATION OF PROCEEDINGS:**

- 8.1 The Applicant is unaware of how many persons throughout Québec were affected by the recalled lots of reagents;
- 8.2 It is estimated that the number of people who can make up the Class are several thousand individuals;
- 8.3 The Applicant[...] does not know, and cannot know the identity of the persons who have been affected by the recalled lot of reagents, especially since medical and pharmaceutical files are confidential;
- 8.4 It would therefore be impracticable to obtain mandates or consolidate proceedings in the present matter;
- 8.5 Furthermore a class action is an appropriate procedural vehicle to give access to justice to and obtain compensation from the Defendants' fault [...] and negligence which has had consequences for thousands of individuals;
- 8.6 The legal issue of whether the Defendants breached their legal obligations towards all members of the class is best dealt with by one judge in a single legal proceeding in order to avoid a multitude of proceedings that would encumber the legal system and potentially lead to contradictory judgements;

9. **THE IDENTICAL, SIMILAR OR RELATED QUESTIONS OF LAW OR OF FACT BETWEEN EACH MEMBER OF THE CLASS AND THE APPLICANT, WHICH APPLICANT WISHES TO HAVE DECIDED BY THIS CLASS ACTION ARE:**

- 9.1 Did Defendant Ortho Clinical Diagnostics fail and neglect to ensure that their HIV tests were free from defects which risk rendering incorrect results?
- 9.2 Did Defendant Ortho Clinical Diagnostics fail and neglect to ensure quality control procedures by manufacturing and distributing HIV reagents generating false negative results?

9.3 Were the Defendants negligent in failing and neglecting to inform the affected patients in a timely manner that there was a risk that their HIV test results were inaccurate?

9.3a) Were the Defendants negligent in failing and neglecting to inform the general public of the recall in a timely manner given that this constituted a serious public health concern for third parties in contact with affected patients;

9.4 Are the Defendants liable to compensate the members of the class for damages suffered?

9.5 If so what is the amount of damages?

9.6 Are the Defendants liable to the Class members for breach of rights guaranteed by the Charter of Human Rights and Freedoms?

10. **THE QUESTIONS OF LAW OR OF FACT WHICH ARE PARTICULAR TO EACH OF THE MEMBERS OF THE CLASS ARE:**

10.1 The only question that is particular to each member of the class is the quantum to which he or she is entitled;

11. **THE NATURE OF THE RECOURSE WHICH THE APPLICANT WISHES TO EXERCISE ON BEHALF OF THE MEMBERS OF THE CLASS IS:**

11.1 An action in damages;

12. **THE CONCLUSIONS SOUGHT BY APPLICANT AGAINST THE DEFENDANTS ARE AS FOLLOWS:**

GRANT the Class Action against the Defendants;

CONDEMN the Defendants to pay to the Applicant compensatory damages, in an amount to be determined, on account of the damages suffered and punitive damages, in an amount to be determined;

THE WHOLE with interest and the additional indemnity provided by law;

CONDEMN the Defendants to any further relief as may be just and proper;

THE WHOLE with legal costs, including the costs of all exhibits, reports, expertise and publication of notices.

13. APPLICANT REQUESTS THAT [...] SHE BE ASCRIBED THE STATUS OF REPRESENTATIVE.

14. APPLICANT IS IN A POSITION TO REPRESENT THE MEMBERS OF THE CLASS ADEQUATELY FOR THE FOLLOWING REASONS:

14.1 The Applicant underwent a blood test for HIV at the Defendant Saint-Mary's Hospital [...] which was done with recalled lots of reagents;

14.2 She has gathered and provided to the undersigned attorneys numerous documents, and has researched the present matter;

14.3 She has the motivation and interest to seek redress for the injustices suffered by class members;

14.4 She has no conflict and is willing and capable of acting in the present matter;

14.5 She has cooperated fully with the undersigned attorneys and is prepared and willing to fully represent and protect the rights of class members;

14.6 Applicant decided to institute a class action instead of an individual action, in order to advance and protect the rights of all class members instead of those of hers alone;

14.7 Applicant has spent numerous hours gathering documents, providing information, and answering questions in the interest of advancing the present matter;

14.8 Applicant is committed to communicating with other members of the class about this matter;

15. APPLICANT SUGGESTS THAT THE CLASS ACTION BE BROUGHT BEFORE THE SUPERIOR COURT FOR THE DISTRICT OF MONTRÉAL FOR THE FOLLOWING REASONS:

15.1 The majority of the Defendants are located in the district of Montréal;

15.2 The Applicant is domiciled in the district of Montréal and to the best of her knowledge, the majority of [...] the class members are domiciled in the district of Montréal;

WHEREFORE THE APPLICANT PRAYS THAT BY JUDGMENT TO BE RENDERED HEREIN, MAY IT PLEASE THIS HONOURABLE COURT TO:

GRANT the present Application;

AUTHORIZE the institution of the Class action;

GRANT the status of representative to Applicant Rachel Dresden for the purpose of instituting the said Class action for the benefit of the following groups of persons, namely:

- a) All individuals who underwent laboratory tests at the Saint-Mary's Hospital, the Lakeshore General Hospital or the Lasalle Hospital between December 2021 and September 2022 which were done with recalled lots of reagents provided by Ortho Clinical Diagnostics and/or OPTILAB Montréal-CUSM and who sustained damages, as a result of the negligence of the Defendants.
- b) All individuals who underwent said laboratory tests who were in fact HIV positive but received negative results.
- c) All individuals who contracted HIV or were placed at risk of contracting HIV as a result of the false negative results provided to individuals in subparagraphs A and B.
- d) The spouses and children of individuals in subparagraphs A, B and C.

IDENTIFY the principal questions of law and of fact to be dealt with collectively as follows:

- a) Was Defendant Ortho Clinical Diagnostics negligent for failing to ensure that its HIV tests were free from defects which risk rendering incorrect results;
- b) Did Defendant Ortho Clinical Diagnostics fail and neglect to ensure quality control procedures by manufacturing and distributing HIV reagents generating false negative results;
- c) Were the Defendants negligent in failing and neglecting to inform the affected patients in a timely manner that there was a risk that their HIV test results were inaccurate;
- d) Were the Defendants negligent in failing and neglecting to inform the general public of the recall in a timely manner given that this constituted a serious public health concern for third parties in contact with affected patients?
- e) Are the Defendants liable to compensate the members of the class for damages suffered?
- f) If so what is the amount of damages?

- g) Are the Defendants liable to the class members for breach of rights guaranteed by the Charter of Human Rights and Freedoms?

IDENTIFY the conclusions sought by the class action to be instituted as being the following:

GRANT the Class Action against the Defendants;

CONDEMN the Defendants to pay to the Applicant compensatory damages, in an amount to be determined, on account of the damages suffered and punitive damages, in an amount to be determined;

THE WHOLE with interest and the additional indemnity provided by law;

CONDEMN the [...] Defendants to any further relief as may be just and proper;

THE WHOLE with legal costs, including the costs of all exhibits, reports, expertise and publication of notices.

DECLARE that any member of the Class who has not requested his/her exclusion from the Class be bound by any judgment to be rendered on the Class action, in accordance with law;

FIX the delay for exclusion from the Class at sixty (60) days from the date of notice to the members, and at the expiry of such delay, the members of the Class who have not requested exclusion be bound by any such judgment;

ORDER the Defendants to provide to Class counsel, in electronic form, a list containing the names and last known coordinates of all individuals who underwent laboratory tests at the Saint-Mary's Hospital, the Lakeshore General Hospital or the Lasalle Hospital between December 2021 and September 2022 which were done with recalled lots of reagents provided by Ortho Clinical Diagnostics and/or OPTILAB Montréal-CUSM;

ORDER the Defendants to the publication of a notice to the members of the Class to be published in La Presse, Le Journal de Montréal, The Gazette, and Le Devoir;

REFER the record to the Chief Justice so that he may fix the district in which the Class action is to be brought and the Judge before whom it will be heard;

THE WHOLE with legal costs, including the costs of all publications of notices.

MONTREAL, March 8, 2023

Annette Lefebvre Avocats

ANNETTE LEFEBVRE AVOCATS

Attorney for Applicant

ORIGINAL

EXHIBITS SUPPORTING THE PLAINTIFF'S AMENDED APPLICATION

In support of the Amened application, the Plaintiff intends to use the following exhibits:

| | |
|---------------------|---|
| EXHIBIT P-1: | Health Product Recall |
| EXHIBIT P-2: | Letter dated November 29, 2022 sent by Defendant OPTILAB Montréal MUHC to the Applicant |
| EXHIBIT P-3: | Article published by CTV News on December 29, 2022, entitled " <i>HIV tests used at Montreal hospitals recalled after suspect results noticed</i> " |
| EXHIBIT P-4: | Ortho Clinical Diagnostics flyer for VITROS Immunodiagnostic Products HIV Combo Reagent Pack and Calibrator |
| EXHIBIT P-5: | Serology results dated January 20, 2022 |

Montréal, March 8, 2023



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COUR SUPERIOR COURT

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ORIGINAL

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